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UNIVERSITY OF GLASGOW

NURSING & HEALTH CARE

MSc (Med Sci)

**The impact of a PICC line on the patient receiving
Modified de Gramont ambulatory chemotherapy.**

Doreen Molloy

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DECLARATION

I, Doreen Molloy declare that this thesis, submitted in fulfilment of the requirements for the award of the Degree of Master's by Research, in the Nursing & Health Care School, University of Glasgow, is wholly my own work unless referenced or acknowledged. The document contains no material which has been accepted for the award of any other degree or diploma in any university.

Signed:

Doreen Molloy

22nd January 2007

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GLOSSARY OF TERMS

5-FU	5-Fluouracil
CVAD	Central venous access device
CVC	Central venous catheter
DLA	Daily life activity
DN	District Nurse
FA	Folinic Acid
IV	Intravenous
MdG	Modified de Gramont
PICC	Peripherally inserted central catheter

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ABSTRACT

Growing demand for cytotoxic chemotherapy has led to restructuring of cancer services in the UK. The majority of patients who receive chemotherapy now do so in the out-patient/ambulatory setting. Ambulatory care is now the fastest growing health-care service delivery model in industrialised nations. The expansion of ambulatory chemotherapy has led to an increase in the use of Peripherally Inserted Central Catheters (PICC lines) which are seen as a cost-effective way of safely administering chemotherapy in the ambulatory setting. The Modified de Gramont (MdG) regimen is one such commonly used ambulatory chemotherapy regimen which requires insertion of a PICC line or other Central Venous Access Device (CVAD) to undertake. Despite the additional care requirements of ambulatory chemotherapy patients, little is known about the ways in which PICC lines impact on the lives of patients and the challenges they face in coping at home with a PICC line in situ.

It was the aim of this study to examine the views and experiences of patients receiving ambulatory MdG chemotherapy via a PICC line, to discover which aspects of living with a PICC line caused most difficulty and to determine if patients viewed PICC lines as a benefit or a burden when receiving ambulatory chemotherapy.

The study was conducted in a large oncology unit in Scotland. A triangulated descriptive study was implemented in two phases over two years. Phase 1 used semi-structured interviews with a convenience sample of 10 MdG patients. The qualitative data were analysed using content analysis and emerging themes identified. The themes were used to construct the questionnaire used in Phase 2 with a convenience sample of 62 MdG patients (response rate 90%). The quantitative data were subject to analysis using Confidence Interval estimation to determine which views were most likely to be held by the population represented by the sample in this study.

The key findings were that the majority of MdG PICC-line patients held favourable views towards having a PICC line and generally adapted well to the experience. The main reported benefits in having a PICC line were the reduced need for venepuncture and cannulation, the ease of chemotherapy administration and not requiring hospital admission to receive chemotherapy. Bathing, showering, hair washing and sleeping caused patients most difficulty when living with a PICC line. The most common fears when living with a PICC line were of the chemotherapy spilling, PICC-line malfunction and the PICC line falling out. Furthermore, a number of challenges in providing informational support to this group of patients were evident as patients reported high information needs yet found the information given overwhelming and at times

unhelpful. Despite this, the biggest majority of patients viewed the PICC line as a benefit not a burden when receiving MdG ambulatory chemotherapy.

CHAPTER ONE - INTRODUCTION

Having spent more than 10 years working within an Oncology setting, I have witnessed first hand how the experience of a diagnosis of cancer impacts upon patients and their loved ones. Furthermore, the associated treatment journey can be a complex and both a physically and emotionally demanding experience. One of the main treatment modalities used in the management of cancer is cytotoxic chemotherapy (Souhami and Tobias 2003), which hereafter is referred to as "chemotherapy".

The number of patients receiving chemotherapy in Scotland has increased greatly over recent years and is predicted to increase even further (Twelves 2001); that is chemotherapy usage increased by 80% between 1993 and 1995 and is predicted to double again in Scotland between 2000 and 2010 (Twelves 2001).

In response to evidence from clinical trials, the use of chemotherapy for a number of common tumour types not previously routinely treated including oesophageal, gastric, pancreatic and non small-cell lung cancer, looks set to expand (Chu and DeVita 2001). In addition, increased understanding of the molecular biology of cancer cells and the ways in which anti-cancer agents affect them, has resulted in a number of advancements in the use of novel treatments such as biological agents, which can be used in combination with existing chemotherapy regimens to improve the efficacy of treatment (Chu and DeVita 2001).

Restructuring of cancer services in the United Kingdom has been necessary to cope with the growing demand for chemotherapy (Twelves 2001) and the majority of patients who receive chemotherapy now do so in the out-patient/ambulatory setting (Young and Kerr 2001; Sitzia and Wood 1998a). Ambulatory chemotherapy involves the administration of chemotherapy in the patient's home. Insertion of a central venous access device (CVAD) such as a Peripherally Inserted Central Catheter (PICC line) is necessary before infusional (IV) therapy can be given safely in the ambulatory setting (Scottish Executive Health Department 2000; Aston 2000). This has meant a huge increase in the use of PICC lines, which are seen as a cost-effective way of safely administering chemotherapy in the ambulatory setting (Galloway 2002; Aston 2000). In the unit where this study took place, PICC line usage is now in excess of 500 per year since they began being used in November 2001. The majority of these patients have a PICC line inserted to undergo the Modified de Gramont (MdG) ambulatory chemotherapy regimen.

The needs of ambulatory chemotherapy patients differ from in-patients since not only do they require additional information regarding the administration of their treatment but also because

they are much more likely to experience difficulties or side effects at home and without expert help close to hand (McCaughan and Thompson 2000; Dougherty, Viner and Young 1998). Furthermore, despite the increase in the number of patients receiving chemotherapy and the increasing complexity of the regimens, there does not appear to have been an associated improvement in the information given to patients (McCaughan and Thompson 2000; Sitzia and Wood 1998a). There may be many reasons for this including the patient's ability to take in information at times of stress and anxiety. However it is concerning that a significant number of patients appear dissatisfied with the information given to them about their cancer diagnosis and chemotherapy treatment despite all the available evidence regarding communicating with people with cancer (Jenkins, Fallowfield and Saul 2001; Jones, Pearson, McGregor, Gilmour, Atkinson, Barrett, Cawsey and McEwen 1999; Mills and Sullivan 1999; Wilkinson 1991).

It was whilst dealing with ambulatory chemotherapy patients with PICC lines that I became aware of what I would describe as additional anxieties in patients. That is to say, patients still had the usual questions and queries regarding their chemotherapy, side effects and so forth that I was used to encountering but they also appeared to have ongoing worries and concerns regarding their PICC lines. Some patients appeared very anxious when the lines were being manipulated and the dressings changed despite the fact that the nurses dealing with the PICC lines were highly skilled and competent in this area. On gentle questioning, patients admitted to being "scared" of the PICC line as the "end of it is in my heart" and they were "frightened of it falling out". One particular patient expressed his disquiet that he was expected to know when something was wrong with the PICC line despite having no medical or nursing experience. Furthermore, some of the issues raised by patients were not necessarily those I would have anticipated; for example, fear of hugging grandchildren and fear of going out shopping in case someone "bumped the line". Another patient had not bathed or showered for more than a month despite recollecting the advice from the nurse who had placed the PICC line that baths were okay provided the affected arm was not fully submerged in the water. Some patients spoke of additional worries associated with having their chemotherapy at home such as the chemotherapy spilling or children and pets coming into contact with the chemotherapy.

This concerned me greatly as it appeared to me that we were not preparing patients adequately for the experience of ambulatory chemotherapy, despite the fact that they would spend most of their time "home alone" with the PICC line/ chemotherapy and away from specialist help and support.

Taking into account the already existing difficulties in giving information to patients undergoing chemotherapy this was not entirely surprising.

In addition, since many of these patients were terminally ill, it was of crucial importance that their lives were as good as they possibly could be and therefore the PICC-line experience needed to be as free from anxiety as possible.

It was my objective to investigate the impact of a PICC line on patients receiving ambulatory chemotherapy in order to contribute to the current understanding and research on the subject matter. The research objectives were thus developed to determine which aspects of living with a PICC line caused patients the most difficulty and what the important issues were for patients. An integrated research design was employed to collect both qualitative and quantitative data to address the research aims. Subsequent discussion of the research findings would add to the existing knowledge base and would enable nurses and other health care practitioners caring for ambulatory chemotherapy patients with PICC lines to make care decisions based on the evidence described.

The aim of this study was to examine the views and experiences of patients receiving ambulatory MdG chemotherapy via a PICC line. The objectives of the study were:

1. To determine which aspects of living with a PICC line cause patients most difficulty.
2. To explore patients' views of the PICC line experience.
3. To determine if patients view PICC lines as a benefit or a burden when receiving ambulatory MdG chemotherapy.

CHAPTER TWO – LITERATURE REVIEW

2.1 Introduction

The overall purpose of this literature review was to explore the impact of a PICC line on patients requiring Modified de Gramont (MdG) chemotherapy in the ambulatory setting. The dearth of literature initially retrieved meant that it was necessary to extrapolate from the wider literature relating to central venous access devices (CVADs) and ambulatory therapy generally. The rationale for this was that PICC lines and other types of CVAD share a number of similarities and both are used in ambulatory therapy. Furthermore, the review demonstrated that similar themes were found in the literature relating to the impact of both PICC lines and other types of CVAD.

The review begins with a brief overview of the MdG chemotherapy regimen and discussion of the commonalities and differences in CVADs to provide context for the study. The impact of CVADs on patients is explored and common themes presented. This is linked to an exploration of the issues surrounding patients undergoing ambulatory chemotherapy and the resulting information needs of patients. The review then concludes with a summary of the review findings and statement of the research aims and objectives.

2.2 Search parameters

The literature search commenced in 2002 using several electronic databases – MEDLINE, Medline In Process and Other Non-Indexed Citations, MEDLINE Daily Update, CINAHL, CancerLit, EMBASE, Cochrane Library, PsycInfo, British Nursing Index, Evidence Based Medicine Reviews and Journals@OVID. The search was limited to articles written in English and was updated on a continual basis. A number of journals were targeted including The British Journal of Cancer, Cancer Nursing, Cancer Nursing Practice, European Journal of Cancer Care, Seminars in Oncology Nursing, Journal of IV Nursing and Journal of Infusion Nursing. The generic internet search engine 'Google' (<http://www.google.co.uk>) was also utilised as a potential source of literature. Government and health organisation websites were accessed and a hand search conducted of the reference lists of papers and documents retrieved for additional literature. In addition, the services of a librarian were used to set up "auto-alerts" from the NHS Scotland e-library to ensure any newly published articles were identified.

Owing to the wide variation in terminology used when referring to CVADs, PICC lines and ambulatory therapy, a number of keywords were searched; peripherally inserted central catheter, PICC line, central venous catheter, tunnelled catheter, Hickman line, non-tunnelled catheter,

central venous access device, central line, implanted port, port-a-cath, patient, psychosocial, education, experience, coping, information, impact, cytotoxic, chemotherapy, de Gramont, modified de Gramont, fluorouracil, 5 FU, ambulatory, home, domiciliary, out-patient, therapy, treatment, oncology and cancer.

The literature retrieved comprised a mix of opinion-based literature, research evidence, educational papers and official reports.

2.3 Quality of existing literature

The literature search produced a wealth of papers in relation to both CVADs generally and PICC lines specifically although it quickly became apparent that there was very little written about how chemotherapy patients cope with or feel about their devices and the impact PICC lines and other CVADs have upon their lives. The literature is replete with papers relating to the technical aspects of PICCs/CVADs including general educational articles (Philpot and Griffiths 2003; Todd 1998; Intravenous Nurses Society 1997; Ryder 1993); the selection and management of CVADs (Aston 2000; Cole 1999; Macklin 1997; Herbst 1996); problems and complication rates (Moreau, Poole, Murdock, Gray and Semba 2002; Walshe, Malak, Eagan and Sepkowitz 2002; Snelling, Jones, Figueredo and Major 2001); placement of PICC lines (Carlson 1999; Goh 1999; Oakley 1997; Cardella, Cardella, Bacci, Fox and Post 1996); drug infusion problems (Collins 2004) and cost implications associated with CVADs (Galloway 2002; Loughran and Borzatta 1995).

The majority of these papers were North American or European where the health care systems differ from that in the UK. Furthermore as PICC lines and CVADs have been used routinely in clinical practice in North America since the 1970s (Aston 2000; Ryder 1993) it was disappointing to find a dearth of nursing research into the ways in which PICC lines and other types of CVAD impact on patients' lives. Very few studies assessed the impact of a CVAD on patients receiving chemotherapy in the out-patient or ambulatory setting. In addition, no studies were identified that specifically examined which aspects of the PICC line/CVAD experience caused patients the most difficulty and the ways in which daily life is affected. This may in part be due to the emphasis placed on measurable outcomes and clinical data prevalent in the field of intravenous (IV) nursing (Hanchett 2001). Hanchett (2001) in a paper which explored the need for infusion nursing theory, stated that IV nursing therapy is considered a technical speciality and that research in this area focused on device placement, site care and drug administration to the neglect of the humanistic aspects of IV nursing. In relation to the UK, it may be that since the insertion, management and ongoing care of PICC lines has been largely developed by nurses (Philpot and Griffiths 2003; Aston 2000; Oakley 1997), the initial focus of research was on

demonstrating safe and effective practice in PICC-line service development and the production of clinical guidelines for managing PICC lines.

Moreover, there was a dearth of UK-based literature which focussed on patients' needs whilst undergoing ambulatory chemotherapy with a CVAD in situ. Many organisations referred to the increase in ambulatory chemotherapy and the importance of supporting patients (Scottish Executive Health Department 2000). Yet there was no evidence-based research as to what the needs of these patients were or the type of support they required. Similarly while Sewell, Summerhayes and Stanley (2002) stated that home-based chemotherapy reduced the stress on patients, afforded them the opportunity to be active in their treatment and encouraged a more positive attitude to chemotherapy, the evidence for these statements was not presented.

The Management and Awareness of the Risk of Cytotoxics Group (marc) produce guidelines on the safe handling of chemotherapy in the ambulatory setting based on the review of research findings and expert opinion (marc 2005). Marc recognised the increase in ambulatory chemotherapy and stated that patients and their carers involved in ambulatory chemotherapy should receive training in the handling and disposal of cytotoxic drugs and what to do in the event of spillage (marc 2005). Whilst evidence existed regarding the safest way to handle chemotherapy drugs, reduce exposure to chemotherapy drugs and safely manage a spill (marc 2005), no evidence was provided as to the most effective way to train patients/carers in safe handling of chemotherapy or how to cope with the added responsibility.

Papers which focussed solely on the technical-management aspects of the devices were rejected in favour of work which focussed on patient-related aspects of living with a PICC line/CVAD and those dealing with the issues concerning ambulatory chemotherapy and the information needs of such patients. Papers concerning paediatric patients or their parents were also rejected.

This left the researcher with a limited number of papers for inclusion in the review. There was no consistency between papers in terms of study design or methods employed. The nursing research tended to involve small, qualitative studies from which the findings were not generalizable. It was necessary to keep these in this literature review since they formed the bulk of the literature available. In addition, it was necessary to extrapolate from the wider literature relating to central venous access devices (CVADs) and ambulatory therapy generally and a number of common themes were identified.

2.4 Overview of central venous access devices

For the purposes of this study it should be noted that a PICC line is a type of central venous access device (CVAD). CVADs are devices whose tip resides in the superior vena cava and are used for the administration of a variety of intravenous (IV) medical therapies (Galloway 2002). Other types of CVAD are implanted ports, tunnelled central venous catheters (CVC), and non-tunnelled central venous catheters (Galloway 2002; Hamilton 2000 and Cole 1999).

The use of CVADs has increased as medical therapies become more complex and ambulatory therapy increases (Moureau et al 2002). Moureau et al (2002) conducted an observational study to determine outcomes in patients undergoing home infusion therapy. They analysed data from a national health care database in California, USA relating to a study population of 50,470 patients from 37 USA states over an 18 month period. The primary study objectives were to identify the types of CVADs in use in home infusion therapy, the types and rates of CVAD complications and the outcomes in managing CVAD complications. It was reported that 93% of patients receiving ambulatory therapy in the home had a CVAD in situ compared with 13% of hospitalised patients and that 51% of the CVADs in situ were PICC lines (Moureau et al 2002).

In excess of five million CVADs are placed in the USA each year (Macklin, Chernecky, Nugent and Waller 2003). No figures could be found relating to the numbers inserted in the UK annually. However individual writers have commented that the number of CVADs generally and PICC lines specifically continue to increase (Aston 2000). Aston (2000) in a paper outlining information for community nurses on how to clinically maintain PICC lines states that in excess of 1,000 PICC lines have been placed in her unit since the conception of a nurse-led service in the late 1990s. Furthermore, activity data from the unit where this study took place also demonstrates such an increase in PICC line usage: that is a steady increase has occurred since November 2001 when PICC lines were first used with in excess of 500 PICC lines now being placed each year, increasing on average by 20% every year.

2.4.1 Tunnelled central venous catheters

Most tunnelled CVCs are made of silicone or polyurethane and are usually inserted under local anaesthetic via the subclavian or jugular vein and threaded though to the superior vena cava (Hamilton 2000). The proximal end of the catheter is tunnelled under the skin to its exit site on the chest wall where a Dacron cuff prevents the device from falling out. Several inches of the catheter thus protrude from the body in this area (Hamilton 2000; Herbst 1996). The end of the catheter has a valve attached which allows the administration of therapies via a needle-free system (Herbst 1996).

2.4.2 Non-tunnelled central venous catheters

These silicone or polyurethane catheters are traditionally used in the critical care setting and are inserted under local anaesthetic via the jugular and subclavian veins (Herbst 1996). Again a length of catheter protrudes from the body and owing to their relative ease of dislodgement, their use is limited to patients who are immobile and require short term central venous access (Hamilton 2000). The administration of therapy is via a needle-free system (Herbst 1996).

2.4.3 Implanted ports

These devices consist of a silicone or polyurethane catheter attached to a reservoir or port made of stainless steel, titanium or plastic (Herbst 1996). Implanted ports are surgically inserted via the cephalic vein under general anaesthetic. A subcutaneous pocket is formed by the surgeon to house the port in position in the chest and the catheter is threaded via the subclavian vein to the superior vena cava (Hamilton 2000). After implantation, access to the patient's venous system is achieved by insertion of a special needle through the patient's skin into the port itself (Herbst 1996). Implanted ports are contained completely within the body although the outline of the sub-cutaneous port can be seen on the chest wall. Furthermore, the needle attachment is visible during the administration of treatment and insertion of the device leaves a visible scar (Hamilton 2000; Herbst 1996).

2.4.4 PICC lines

These silicone or polyurethane catheters are inserted under local anaesthetic via the basilic, cephalic or median antecubital veins in the patient's arm and threaded upwards into the superior vena cava (Oakley, Wright and Ream 2000; Herbst 1996). A length of catheter exits the patient's body from the antecubital space and as with all other CVADs with the exception of an implanted port, therapy is administered via a needle-free system (Herbst 1996).

PICC lines have been available for use in the UK since 1994 although they have been widely used in the USA since the 1970s (Aston 2000). PICC line use in the UK is largely within the specialties of haematology, oncology, parenteral nutrition and HIV/AIDS (Todd 1998) but other disciplines such as cardiology and orthopaedics are showing interest in using PICC lines to treat patients on medium to long-term antibiotics (Aston 2000).

In the chemotherapy setting, cytotoxic agents are administered via PICC lines by intermittent bolus injection, intermittent infusion and continuous infusion (in conjunction with an infusional pump).

2.4.5 Commonalities of CVADs

All CVADs must be placed by an appropriately trained practitioner and constitute a medical device which breaches the body's boundaries (Macklin et al 2002; Cole 1999). All CVADs have the potential to cause complications and require ongoing care and maintenance. Thus CVADs impact on the patient's life although the extent and nature of this varies with the device inserted. Informed consent must be obtained prior to placement (Cole 1999).

2.4.6 Differences of CVADs

The main differences between CVADs relate to the following areas.

Direct and associated costs

CVADs vary in terms of the actual cost of the device, its associated paraphernalia and insertion and maintenance costs (Galloway 2002; Dobson 2001; Cole 1999). Insertion costs are greater with implanted ports than with tunnelled CVCs, non-tunnelled CVCs and PICC lines since implanted port insertion requires the use of an operating theatre, surgeon and supporting staff (Aston 2000; Cole 1999; Herbst 1996). Similarly, implanted ports are the most expensive devices per se with PICC lines being the least expensive. The ongoing care and maintenance costs vary not only with device, but also with provider and are beyond the scope of this literature review but require consideration by service providers (Galloway 2002; Dobson 2001 and Todd 1998).

Placement/siting

The method of placement for each type of CVAD has been described above. Tunnelled CVCs usually exit the chest area, non-tunnelled CVCs the neck and PICC lines, the arm. Implanted ports have no exit site and thus are the least visible of all CVADs. Implanted ports are the only CVAD which require the use of an operating theatre and general anaesthetic for insertion/removal as all others can be placed/removed 'by the bedside' or in the X-ray department under local anaesthetic (Galloway 2002; Dobson 2001; Aston 2000).

Longevity

Although variations occur with individual patients, the accepted lifetimes of the CVADs are as follows;

Non-tunnelled CVCs:	less than three months
PICC lines:	less than 12 months
Tunnelled CVCs:	approximately one year
Implanted ports:	up to two years

(Galloway 2002; Dobson 2001; Cole 1999; Herbst 1996).

Treatment associated differences

PICC lines have a narrow lumen and are less suited to frequent blood sampling and administration of blood and blood products (Aston 2000; Herbst 1996). If multiple interventions such as these are likely to be required, a tunnelled CVC is recommended (Aston 2000; Todd 1998).

Associated complications

PICC insertion avoids several of the potential difficulties associated with the placement of tunnelled and non-tunnelled CVCs such as pneumothorax and great vessel perforation and the general risks of surgery associated with implanted port insertion (Todd 1998). No clinical trials or meta-analyses could be found which systematically compared different CVADs in terms of associated complications although individual studies presented data on commonly reported complications. Commonly reported complications for all CVADs include device-related infection, CVAD occlusion, CVAD displacement/migration and venous thrombosis (Moureau et al 2002; Herbst 1996). The nature and frequency of associated complications varies with CVAD type and occurs in part due to the differing mechanics and workings of the devices (Moureau et al 2002). PICC lines and non-tunnelled CVCs are associated with higher rates of dislodgement than tunnelled CVCs and implanted ports owing to their narrower lumen and relative instability (Moureau et al 2002; Dobson 2001; Cole 1999 and Herbst 1996). Similarly, occlusion is more of a risk with PICC lines owing to their narrow lumen (Herbst 1996). Infection rates are also reported to vary widely (Snelling et al 2001) between different devices in individual studies but since none of these have been randomised, it is not possible to rule out other factors such as the patients' underlying disease status as contributory factors (Snelling et al 2001).

Owing to the differences between CVADs, a number of considerations are given to device placement and are summarised below.

Treatment-related considerations: the type and duration of treatment prescribed and the frequency of access required. PICC lines are not recommended for therapies lasting more than 12 months or if frequent blood sampling/infusion of blood products is anticipated (Dobson 2001; Cole 1999; Herbst 1996). In these instances, an implanted port or a tunnelled CVC is recommended (Dobson 2001; Cole 1999; Herbst 1996).

Organisational- related considerations: the availability of appropriately trained staff to place the CVAD and provide ongoing care, the associated costs and the CVADs available in the clinical area all influence the range of CVADs available to patients who require them (Dobson 2001; Cole 1999; Herbst 1996). Choice is restricted if appropriately trained staff are not available to place a particular device or if a device is deemed to expensive to be purchased by the service provider (Galloway 2002).

Patient-related considerations: physical and anatomical contra-indications to a particular CVAD may rule out its use. For example, anatomical distortions such as bulky axillary lymph nodes or lymphoedema may contra-indicate a PICC line (Todd 1998) whereas an allergy to available dressings may necessitate an implanted port (Dobson 2001). In addition, the ability and willingness to participate in ongoing care and monitoring of the CVAD, patient lifestyle and patient preference also influence the type of device placed (Dobson 2001; Cole 1999; Herbst 1996) and this is discussed in more detail in subsequent sections.

In summary, CVADs share a number of commonalities and differences and have associated advantages and disadvantages. The decision as to which CVAD to employ during the course of a patient's treatment is made on the grounds of the duration of therapy, therapy to be administered, ongoing care requirements and patient choice issues (Herbst 1996). Furthermore, CVADs differ in terms of how they are placed and where they exit the body. Therefore patient preference may draw them towards a particular type of CVAD (Dobson 2001). Non-tunnelled CVCs are excluded from the remainder of this review since their use is confined to the acute hospital in-patient setting and this is not the focus of this study.

2.5 Modified de Gramont chemotherapy regimen

Colorectal cancer remains the second most common cause of cancer-related death in Europe since it is incurable once the disease has spread (Leonard, Scymour, James, Hochhauser and

Ledermann 2002). The cytotoxic agent 5-Fluorouracil (5-FU) is relatively non-toxic and has been the mainstay of chemotherapy for colorectal cancer for more than 20 years (Souhami and Tobias 2003; Leonard et al 2002). The National Institute for Health and Clinical Excellence (NICE 2005) and the Scottish Intercollegiate Guidelines Network (SIGN 2003) both recommend '5-FU containing' regimens as first line treatment in colorectal cancer. Newer cytotoxic agents such as Irinotecan and Oxaliplatin showed promise in increasing survival in advanced colorectal cancer but as yet none have been shown in clinical trials to be superior to 5-FU (NICE 2005; Souhami and Tobias 2003).

Treatment with 5-FU can be given in a variety of ways (Souhami and Tobias 2003) and it is known that the response to 5-FU in advanced colorectal cancer is increased by the concomitant administration of folinic acid (FA) (Leonard et al 2002; de Gramont, Louvet, Andre, Tournigand and Krulik 1998). De Gramont et al (1998) reported the findings from a meta-analysis of nine randomised controlled comparative clinical trials carried out over a decade which involved 1,381 patients with advanced colorectal cancer. The trials compared single agent 5-FU regimens with regimens containing 5-FU and FA. The regimens containing the 5-FU/FA combination demonstrated significantly improved tumour response rates (23% versus 11%; odds ratio 0.45; $p < 10^{-7}$) although overall survival was comparable with the two treatment arms (11.5 months for 5-FU/FA; 11 months for 5-FU alone; $p = 0.57$).

A number of regimens exist incorporating both 5-FU and FA which differ in terms of the method of administration and doses of the drugs used (Leonard et al 2002). Two standard regimens are the de Gramont regimen (two-hour infusion of FA, followed by bolus injection of 5-FU followed by 22-hour infusion of 5-FU with the same sequence repeated on the second day, repeated fortnightly) and the Mayo Clinic regimen (five-day bolus 5-FU/FA followed by three rest weeks, repeated for six cycles) (Cheeseman, Joel, Chester, Wilson, Dent, Richards and Seymour 2002). These two regimens were compared in a randomised controlled trial involving 448 patients with advanced colorectal cancer which demonstrated that the de Gramont regimen showed better response rates (32.6% vs 14.4%; $p > 0.0004$) and median progression-free survival (27.6 vs 22 weeks; $p > 0.001$) with significantly reduced rates of diarrhoea, mucositis and neutropenia also in the de Gramont arm (figures not supplied in the paper) (Cheeseman et al 2002).

Following this trial, the de Gramont regimen was adopted as standard therapy by many oncologists in the UK and France (Cheeseman et al 2002). This classic 'de Gramont' regimen is administered thus;

- two-hour infusion of FA
- bolus 5-FU
- 22-hour infusion of 5-FU

This is administered on two consecutive days every fortnight, usually by standard peripheral venous cannula, and requires admission to hospital and at least one overnight stay (Cheeseman et al 2002).

More recently, the de Gramont regimen has been superseded by other regimens which have been developed to maintain the efficacy and safety profile of de Gramont but which are more convenient for patients and less demanding of health care resources (Cheeseman et al 2002). These so called 'modified de Gramont' regimens (MdG) also have the additional advantage of not requiring an overnight stay in hospital (Cheeseman et al 2002; Leonard et al 2002).

MdG regimens preserve the main elements of de Gramont by providing dose intensive exposure to 5-FU every two weeks (Leonard et al 2002) but are a more practical regimen which only require the FA infusion and 5-FU bolus to be given on day one with the infusion of 5-FU administered via an ambulatory pump over 46 hours (Cheeseman et al 2002). Thus patients need only attend hospital on day one of the regimen and no overnight stay is required. It is noted however that MdG regimens require the insertion of a CVAD to allow the 46-hour infusion of 5-FU to be administered safely in the ambulatory setting (Scottish Executive 2000; de Gramont et al 1998). MdG is a well tolerated regimen which patients find acceptable as it avoids admission to hospital (Cheeseman et al 2002). Cheeseman et al (2002) also stated it reduced hospital costs, was less intensive of human resources and promoted better working practices between the community and the oncology centre since community staff were more involved in the care of the patients (Cheeseman et al 2002). However, as discussed in section 2.3, the evidence presented to support these statements was anecdotal.

In the unit where this study took place, patients receiving MdG have a PICC line placed in the week prior to chemotherapy commencement. Patients then attend the unit on day one of the regimen where FA is given as a two-hour infusion. This is followed by a bolus of 5-FU. Finally, a 46-hour 5-FU infusion pump is attached to the patient's PICC line which they go home with to be disconnected by the community nurse on completion of the infusion. This sequence is repeated until completion of treatment.

2.6 Impact of central venous access devices on patients

This section examines the literature regarding the impact of implanted ports, tunnelled CVCs and PICC lines on patients. Existing literature relating to each device is presented individually followed by a summary of the key themes which emerged.

2.6.1 Impact of CVADs on patients generally

Two papers were retrieved which discussed patient-related issues regarding having a CVAD in ambulatory care. These were an educational paper (Cole 1999) and a paper which reported on service delivery (Dobson 2001), both of which presented mainly anecdotal evidence on the issues the authors believed to be important. Although no data was collected, the authors based their views on literature review findings, personal opinion and expertise of the subject area.

Cole (1999) described the selection and management of CVADs in the ambulatory setting in the USA based on his expertise as a Clinical Coordinator for Home Care. Cole refers to the literature available and draws on personal experience to argue that issues which confront the patient with a CVAD in the home care setting need close examination. Cole (1999) states that the impact of CVADs on patients can be considerable and that patient choice should be a major factor in CVAD selection. Factors such as insertion procedure, ongoing care requirements, appearance after insertion and the patient's activity level are discussed in relation to their importance in CVAD selection. Cole states that a CVAD can negatively impact on the patient's body image and expose them to questions about their disease/treatment that they would rather not answer. Furthermore, patients may not have the necessary physical and cognitive ability to take part in the ongoing care or at least observation of a CVAD, nor have a home environment suitable for such a device to be managed. Cole (1999) concludes by that health care professionals need to be more aware of the potential patient impact of CVADs, particularly in the ambulatory setting owing to the complexities of the care situation. This is a laudable statement to make but the inclusion of evidence-based literature in Cole's (1999) paper would have strengthened his argument.

Similarly, Dobson (2001) in a paper which described a model designed to outline factors to be considered when setting up an ambulatory therapy programme, stressed the considerable impact of CVADs on patients. It is not clear from the paper how the model was developed although it appears to be used by the ambulatory therapy team in the author's Australian hospital. In keeping with Cole (1999), Dobson (2001) stated that patients required a sufficient level of physical and cognitive ability to cope with the demands of having a CVAD at home. Dobson's experience was that the insertion of a CVAD and the resulting altered body image was a great concern to many patients to the extent that some refused to have a CVAD. Other patients felt

the "attachment" was a constant reminder of their disease status and those initially accepting may go on to reject the device (Dobson 2001). As with Cole (1999), Dobson's (2001) paper is limited by a lack of evidence-based research to back up many of her claims although again the content appears to be based on extensive experience within the field. Thus both Cole's (1999) and Dobson's (2001) views are worthy of consideration and both authors highlight the considerable impact a CVAD has on patients and the need for more research regarding the impact on patients of medical devices such as CVADs.

The need for more research into the challenges faced by patients when faced with health-related technology was also discussed by Marden (2005). The focus of Marden's (2005) work was to develop a theoretical model as a framework for inquiry into factors affecting people's responses to therapeutic health technology but several points pertinent to this literature review were discussed. Technology dependence was defined as reliance on any form of drugs, equipment or device in order to treat health problems (Marden 2005). Thus reliance on a CVAD clearly constitutes technology dependence by this definition. Marden concurred with the findings of Sandelowski (1997 and 1993) who conceptualized that dependence on health-related technology could both positively and negatively impact on a patient's quality of life; and Locsin (1995) who stated that technology can potentially alienate patients from nurses and thus widen the gap between them. Again the papers of Marden (2005), Sandelowski (1997, 1993) and Locsin (1995) were theoretical and based on personal observations and literature review findings but nonetheless they all concluded that further research regarding the impact of health technology on patients should be considered an important focus for future nursing research.

2.6.2 Impact of implanted ports on patients

The literature search yielded four articles which considered the impact of implanted ports on adult patients.

Borst, de Kruif, van Dam and de Graaf (1992) used a descriptive design to evaluate the satisfaction of patients and their experiences with an implanted port. The study took place in an academic hospital in the Netherlands and involved patients receiving chemotherapy for advanced cancer. A convenience sample of 25 female and 15 male patients completed a structured questionnaire during a telephone interview. The questionnaire was adapted from a previous study where the instrument was used to measure satisfaction with a tunneled CVC. The validity and reliability of the tool was not reported. The authors stated that "the psychometric properties of the instrument proved to be satisfactory" but provided no statistical evidence of how this was achieved. Borst et al found that almost all patients were very satisfied with the implanted port and that it did not interfere with daily life activities. Other advantages

reported by patients were that insertion of the implanted port meant they could receive ambulatory chemotherapy and that the implanted port reduced the number of peripheral venepunctures required. However, although the majority of patients reported that the implanted port conserved their body image, 23% of patients (n=9) stated that the port served as a constant reminder of their illness and 13% (n=5) felt frightened by the implanted port being in their body. Borst et al concluded that although 95% of patients (n=38) felt that the advantages outweighed the disadvantages, pre and post-implantation information should be reviewed as 40% of patients (n=16) felt unprepared for certain aspects of the experience.

Bow, Kilpatrick and Clinch (1999) conducted a prospective randomized controlled trial to examine the safety, efficacy, costs and impact on quality of life of implanted ports in chemotherapy patients. The study findings regarding impact on quality of life are reported here, in keeping with the purpose of this review. Patients were randomly allocated at the start of treatment to receive chemotherapy via an implanted port (study group) or by standard peripheral cannula (control group) (Bow et al 1999). The Functional Living Index-Cancer (FLI-C), a well-validated standardized 22-item questionnaire was used with a randomized sample of 92 patients to address quality of life. Bow et al found that the implanted port patients reported less anxiety and discomfort with venous access than the control group. This is in keeping with Borst et al (1992) who reported the reduced need for peripheral venous access to be one of the main advantages of an implanted port. However, Bow et al found no statistical differences in the FLI-C scores between the implanted port group and the control group demonstrating that no measurable improvement in quality of life could be attributed to the implanted port. It was reported further that the majority of patients' FLI-C scores indicated a chemotherapy-related decrease in quality of life ($p < 0.0001$) in both the implanted port patients and the control group.

A later study undertaken by Chernecky (2001) also addressed quality of life in implanted port patients. Chernecky (2001) used a descriptive design to examine cancer patients' satisfaction/dissatisfaction with implanted ports and to identify positive and negative experiences on patients' quality of life. The study took place in an oncology out-patient clinic in the USA. A convenience sample of 24 patients undergoing chemotherapy completed a questionnaire developed by the researcher. Data was collected on overall 'happiness' with the implanted port and likes and dislikes associated with it. Patients were also asked whether the implanted port had improved their quality of although no actual quality of life assessment tool was used.

Chernecky (2001) found that patients experienced "overwhelming" satisfaction with their implanted port and 22 patients (92%) stated their quality of life was improved as a result of

having an implanted port. The top three reasons reported by patients as to why they liked the implanted port were reduced pain of venous access (n=7, 29%), reduced frequency of venepuncture (n=6, 25%) and greater ease of drawing blood (n=3, 12%). Other less frequently reported likes regarding the implanted port (numbers not reported in paper) were freedom of arms during treatment and that the implanted port was low maintenance. Although 71% of patients (n=17) stated that they could see no disadvantages at all with the implanted port, a small number of dislikes were reported. These were monthly heparinization (n=2, 8%), difficulty sleeping (n=1, 4%), reluctance on non-oncology personnel to access the port, pain at the site of the port and the psychological effects of having something foreign in the body (numbers not reported in paper).

Chernecky (2001) concluded that in view of the strong positive impact of the implanted port and the reported improvement in quality of life, nurses should encourage the use of implanted ports earlier in the treatment journey. This is a fairly strong recommendation to make on the basis of one small, descriptive study but Chernecky justified this on the grounds of the consistency and strength of the positive responses and because the study patients all had previous experience of chemotherapy administration via the peripheral route; in other words without an implanted port. This meant all had insight into life both with and without an implanted port yet the majority of patients (n=22, 92%) thought the implanted port increased their quality of life when undergoing chemotherapy.

This is in contrast to Bow et al (1999) who found no increase in quality of life with an implanted port in situ. It is interesting to note that the patients in Chernecky's (2001) study had experience of receiving chemotherapy both via standard peripheral cannula and via implanted port whereas the patients in Bow et al's (1999) study had experience of only one of these methods. Thus Chernecky's study patients were comparing their quality of life when receiving chemotherapy with a port against their prior experience of chemotherapy administration without a port. Bow et al's patients on the other hand were reporting their overall chemotherapy-related quality of life, irrespective of the method of administration, and therefore were potentially biased towards a negative impact on quality of life as reflected in the FLI-C scores for both the port and the control group.

Chernecky's (2001) questionnaire was adapted by Goossens, Vrebos, Stas, De Wever, and Frederickx (2005) for use in a prospective study which aimed to collect the positive and negative experiences of patients with an implanted port and to investigate the impact of the implanted port on their overall quality of life. The study took place in the out-patient department of a university hospital in Belgium and used a convenience sample of 106 patients

undergoing chemotherapy for an oncological or haematological malignancy. The questionnaire was completed by 98 patients (92.4% response rate). Although Goossens et al (2005) state that their instrument was adapted from Chernecky's (2001) study it is not possible to comment on the extent of similarity or difference between the tools since neither is presented in the literature.

Goossens et al's (2005) questionnaire comprised four questions relating to how long the implanted port had been in situ and whether peripheral chemotherapy had previously been given, problems associated with the implanted port, effect of the implanted port on quality of life and the positive and negative experiences in relation to implantation of the port. Content reliability was confirmed by comparing the patients' responses with the researcher's a priori information gained from personal experience and the relevant literature.

In keeping with Borst et al (1992), Bow et al (1999) and Chernecky (2001), Goossens et al (2005) found that patients reported the positive impact of the implanted port stemmed from the reduced need for peripheral venepuncture and cannulation. More positive experiences in relation to IV access with the implanted port were reported by 49% of patients (n=48). Lesser reported positive experiences were the increased freedom during chemotherapy (n=5), a feeling of happiness with the implanted port (n=5) and also that the experience was "easy" (n=5). Negative experiences were reported as being the visibility of the sub-cutaneous hub of the implanted port (n=20, 20%), general discomfort (n=11, 11%), sleep disturbance (n=5, 5%) and the association of the implanted port with the disease of cancer (n=4, 4%). Also in keeping with Borst et al (1992), Goossens et al found that 22% (n=22) of patients reported being unprepared for both the insertion procedure and the resulting post-insertion experience despite the information given pre-insertion.

Furthermore, consistent with Bow et al (1999), Goossens et al's (2005) study was not able to demonstrate a positive impact on patients' quality of life. Only 8% of patients (n=8) in Goossens et al's study reported a positive impact on quality of life as a result of the implanted port. In addition, 17% of patients (n=17) in Goossens et al's study reported a negative impact on quality of life associated with the implanted port. The majority of patients (88%) in Goossens et al's study who reported a positive impact on quality of life were aged 54 years or more whereas the majority of patients (65%) who reported a negative impact on quality of life were less than 54 years of age. The authors tentatively suggest that this tendency towards a negative impact on quality of life may be related to the perception of port visibility on the chest area being more important in younger patients. It was not possible to consider if age was a factor in Bow et al's (1999) or Chernecky's (2001) studies since the ages of the study participants was not given or commented upon.

Thus despite the dissimilarities in the design of studies reviewed relating to the patient-impact of implanted ports, a number of common themes are evident. Patients reported one of the major advantages of an implanted port to be the reduced need for peripheral venepuncture and cannulation which is a source of discomfort and distress to the majority of chemotherapy patients. Furthermore, implanted ports appear to have limited impact on daily life and body image and are generally viewed by patients as being an acceptable means of chemotherapy administration. The disadvantages associated with implanted ports relate mainly to general discomfort associated with device placement, the psychological effects of having a foreign medical device in the body and information giving pre and post insertion.

2.6.3 Impact of tunnelled CVCs on patients

Three studies which explored the impact of tunnelled CVCs on adult patients were retrieved.

Thompson, Kidd, McKenzie, Parker and Nixon (1989) conducted a study in a large teaching hospital in Edinburgh to solicit patients' views on the effects tunnelled CVCs had on their day to day lives. A convenience sample of 24 haematological cancer patients with a tunnelled CVC in situ completed a questionnaire developed by a group of surgeons, haematologists and nurses. The questionnaire collected patients' views regarding tunnelled CVC insertion, effect of tunnelled CVC on clothing, personal hygiene, body image, relationships, employment and leisure activities.

Thompson et al (1989) found that the tunnelled CVC had an impact on patients' day to day lives in a number of ways. The majority of patients (n=20) reported the external component of the tunnelled CVC to be too bulky and the dressing to cause discomfort (n=16). More than half of the patients (n=14) felt the tunnelled CVC had affected the way they dressed. In terms of daily activities, the 12 patients who could drive continued to do so although 10 patients had to discontinue sporting activities. Of the 19 patients in employment, only three had stopped working with 16 able to continue. Other effects were that body image was negatively affected (n=5), partners were negatively affected (n=10), families were upset (n=4) and that the tunnelled CVC was a reminder of illness (n=15).

Insertion of a tunnelled CVC proved troublesome for the majority of patients (n=20) in Thompson et al's (1989) study. The main complaints were discomfort during the procedure (n=11), feeling "smothered" during the procedure (n=10), post-procedure pain (n=10), suture discomfort (n=10) and that the insertion took too long (n=9). Positive effects however were reported regarding the ease of chemotherapy administration (n=20) and a reduction in

chemotherapy-associated phlebitis (n=17). Furthermore almost all patients (n=23) stated that they would accept the same device again if required; suggesting that despite the difficulties encountered the overall experience was acceptable.

A study which aimed to investigate complications and patient satisfaction with tunnelled CVCs over a six year period at the Netherlands Cancer Institute was conducted by Claessen, De Vries, Huisman, Dubbelman, Van Rheenen, Van Dam and De Graaf (1990). A total of 120 tunnelled CVCs were inserted in 104 adult patients with cancer from which a convenience sample of 30 patients was invited to complete a quality of life questionnaire. The questionnaire was returned by 24 patients. No detail is given as to the content of the questionnaire other than to say it was a measure of quality of life.

Claessen et al (1990) found that the majority of patients (n=18) did not experience any problems with the tunnelled CVC that affected quality of life and/or dressing. Only four patients reported difficulties concerning ongoing care of the tunnelled CVC at home. The main enhancement to quality of life associated with the tunnelled CVC was the reduced need for venepuncture and cannulation as reported by 19 patients. Claessen et al concluded that tunnelled CVCs have an acceptable complication rate and a high degree of patient satisfaction and should be considered for use in the early stages of anti-cancer treatment.

Daniels (1995) reviewed the tunnelled CVC literature in relation to the physical, psychological and social implications of the devices following her concerns that patients' needs were not being addressed. No information is given in the review paper regarding the search parameters used nor is mention made as to the methodologies employed in any of the articles reviewed. Daniels (1995) states that there was a dearth of information relating to the impact of tunnelled CVCs on patients and that most of the literature published concerned the medical and technical aspects of tunnelled CVCs such as infection control and complications. Thus it was necessary for Daniels to draw on the literature regarding other comparable situations in order to analyze the potential impact on patients. Daniels goes on to extrapolate from literature relating to allied concepts such as the stress on patients requiring an invasive procedure and the physical and psychosocial impact of cancer and the effects of treatment.

Daniels (1995) found that despite the fact that an invasive procedure such as the insertion of a tunnelled CVC could potentially exacerbate an already stressful situation for a patient requiring IV therapy; the implications for patients were largely overlooked. The potential for tunnelled CVCs to impact negatively on both physical and psychosocial wellbeing is stated although much of the discussion is discursive and anecdotal rather than evidence-based. Daily life

activities such as dressing, socialising and wearing a seat belt are highlighted as being problematic. Similarly it is proffered that tunnelled CVCs may serve as a reminder of diagnosis and the need for treatment and may negatively impact on body image but again the evidence is mainly anecdotal. Finally, the additional informational requirements for patients requiring a tunnelled CVC are highlighted as an area of unmet need and Daniels (1995) concludes the review by stating that further research into the patient impact of devices such as tunnelled CVCs is required.

Daniels (1996) went on to conduct a follow-up study to explore the impact of tunnelled CVCs on patients and their families in order to influence future nursing care and practice. Daniels (1996) developed a questionnaire for use in a 'guided' interview although no detail is provided regarding the steps taken in questionnaire development or how the questionnaire content was decided. A convenience sample of 12 male and nine female adult cancer patients with a tunnelled CVC attending a regional cancer centre in the UK took part in the study. The questionnaire served as an interview guide and was used to gather data relating to tunnelled CVC insertion, patient education, patient coping and the physical and psychosocial impact of the CVC. The study results demonstrated that patients had a variety of informational needs in relation to tunnelled CVC placement and that the tunnelled CVC impacted on patients' lives in a number of ways. For example, the insertion procedure proved traumatic for the majority of patients (n=19) and it was further stated that the information provided pre-insertion did not equate with the patients' actual experiences. Ongoing continuity of care between the regional centre and the community was also problematic at times and a lack of community expertise in relation to tunnelled CVCs meant that patients also required ongoing support from the regional centre.

In terms of psychosocial/physical impact, in contrast to Claessen et al's (1990) study, Daniels (1996) reported that 90% (n=19) of patients felt the tunnelled CVC had affected the way they dressed. For example, some patients had to alter or modify existing clothing and others felt the need to dress in such a way as to conceal the CVC. Other difficulties included sleeping and bathing problems, a fear of being in crowds and difficulties participating in sports although the number of patients affected is not given. A change in body image as a result of the tunnelled CVC was not identified by the majority of patients as they reported that their body image had been affected by the entire cancer/treatment experience; for example, chemotherapy induced alopecia. A small number of patients however were discontented that the tunnelled CVC had left them with a physical scar and one man had been unable to engage in sexual activity as his partner could not accept the tunnelled CVC. Furthermore as was found with the implanted port

patients (Chernecky 2001; Borst et al 1992), six patients stated that they felt anxious about the tunnelled CVC being in their body and about the ongoing care of the CVC.

Despite the difficulties encountered by patients, Daniels (1996) concluded that tunnelled CVCs had less impact than she had previously imagined and that the majority of patients coped well with the experience. It was noted however that some patients reported a difference between prior information received and the actual experience in keeping with Borst et al (1992). This may have been owing to the patients' overall difficulties in coping with information at a stressful time. In keeping with Claessen et al (1990) the reduced need for venepuncture and cannulation brought about by the tunnelled CVC being in-situ was highlighted as a particular advantage.

Thus it can be seen that the literature relating to the patient-impact of tunnelled CVCs is inconclusive. The papers reviewed demonstrate that although similar themes have been discussed in various studies, the findings are at times inconsistent. Furthermore the common themes presented are in keeping with those discussed in the previous section on implanted ports suggesting some commonalities in patient-impact between the two types of device.

2.6.4 Impact of PICC lines on patients

Only three articles were retrieved which explored the patient-impact of PICC lines.

Oakley, Wright and Ream (2000) conducted an exploratory study in a UK hospital to investigate patients' and nurses' experiences of a nurse-led PICC line service. A convenience sample of 10 ambulatory chemotherapy patients and 10 nurses took part in the study. The patients were interviewed twice; once within 24 hours of PICC line insertion and then three to four weeks following insertion. The nurses were interviewed once to determine their experiences of PICC lines, collaborative working and their preparation for managing PICC lines. Oakley et al (2000) state that the interviews were guided by schedules of open and closed questions but no further detail is provided regarding the development or content of the interview guides.

Oakley et al (2000) found that although patients generally appeared to adapt well to having a PICC line in situ, a number of difficulties were evident. The most common difficulties reported by patients were bathing (n=10), sleeping (n=7) and dressing (n=5). Of the six patients who worked prior to PICC line insertion, five had stopped as the PICC line made manual work impracticable. In addition, all patients stated that protection of the PICC line caused anxiety with two patients also reporting an impact on socialising for fear of the PICC line being

damaged in some way. Interestingly, the majority of nurses (n=9) also reported protection of the PICC line to be an important consideration with 50% of nurses (n=5) further stating that the PICC lines were “fragile”, which could have implications on how patients view PICC lines. In terms of PICC line impact on body image, Oakley et al (2000) found only one female patient to be affected negatively which the authors’ state may have been because the study was conducted in the winter months when the use of long sleeved clothing makes concealment of the PICC line easier. Several of the nurses also believed that PICC lines could impact negatively on body image, especially during warm weather when less clothing was worn.

A further finding from Oakley et al’s (2000) study was that despite the education and advice given to patients pre PICC line insertion, the majority of patients (n=7) did not seem to know what to expect on discharge home. This mismatch between information given and resulting experience is in keeping with previously discussed findings (Goossens et al 2005; Daniels 1996; Borst et al 1992) and has been highlighted in educational papers on the challenges of using CVADs in ambulatory therapy (Macklin et al 2003; Moureau et al 2002; Cole 1999; Herbst 1996). Despite the difficulties encountered, Oakley et al (2000) concluded that patients viewed PICC lines as beneficial with any inconvenience encountered overridden by the necessity to have treatment. A limitation of Oakley et al’s (2000) study however is that four weeks is a relatively short period of time in which to investigate the experience of living with a PICC line, something recognised by the authors who suggested further research be carried out with patients who had PICC lines in situ over longer periods of time. As an exploratory study, Oakley et al (2000) provided evidence of the type of difficulty experienced by their study patients. They also recommended further research into how ambulatory chemotherapy PICC-line patients adapt to their situation and the best ways to educate and support patients through the experience.

A further study which found that PICC lines were well accepted by patients was that of Gabriel (2000). Gabriel conducted a small qualitative study using a convenience sample of 15 patients attending a UK hospital to identify patients’ perceptions of the effect of a PICC line on their quality of life. Patients with a range of conditions who required a PICC line for the administration of antibiotics, blood products and chemotherapy were included to eliminate the underlying disease and treatment as potential confounding variables. The data were collected from participants in three ways; by interview prior to PICC line insertion, by weekly self-report questionnaires for the duration of PICC placement and by a further interview 14 days after PICC line removal.

As with previous papers reviewed, the methodological detail provided in Gabriel’s (2000) paper is scant and the content of the interview schedules and questionnaires is not clear. Gabriel

states however that a phenomenological approach was taken in the first interviews which gathered data relating to the perceived effects of the PICC line on the patients' lives, whilst grounded theory was used in the second interviews to allow patients to reflect on the impact of the PICC line on their quality of life. The weekly questionnaires gathered data relating to the patients' wellbeing and experiences with the PICC line in situ.

In keeping with the findings of Oakley et al (2000), Gabriel (2000) found that lifestyle was relatively unaffected by the PICC line although one patient did comment that she was unable to enjoy a daily soak in the bath with the PICC line in place. The patients in Gabriel's (2000) study reported that the PICC line had improved their quality of life for the duration of the treatment although as with other studies (Chernecky 2001; Goossens et al 2005) no actual validated tool for measurement was used. Furthermore, it is interesting to note that all of the patients in Gabriel's (2000) study experienced prior problems with venous cannulation and were therefore potentially biased favourably towards a PICC line since it avoided the need for frequent cannulations. Indeed one of the most prominent findings of Gabriel's study was that patients reported the main benefit to quality of life was the reduced need for repeated cannulations owing to the PICC line being in situ. It could therefore be argued that it was the lack of repeated cannulations that gave patients an improved sense of quality of life and not the actual PICC line per se. In other words, any intervention which meant they did not require repeated cannulations could have had the same effect.

A follow up paper by Gabriel (2003) aimed to identify the acceptability of PICC lines to patients undergoing chemotherapy and to ascertain if they had been involved in device selection. Gabriel (2003) re-examined the original interview data from the nine chemotherapy patients who had taken part (Gabriel 2000) using Giorgi's approach to data analysis. Gabriel (2003) found that chemotherapy patients accepted PICC lines and reported PICC lines to have little effect on lifestyle, body image or comfort. Furthermore chemotherapy patients reported that they had felt involved in the decision to have a PICC line placed as opposed to continuing with peripheral venous cannulation or having another type of CVAD placed. Gabriel (2003) highlights patient choice in the CVAD decision making process as being a positive indicator for PICC line acceptance although again it could be argued that since patients chose the PICC line they are more likely to hold a favourable opinion of it once in situ. In keeping with her earlier (2000) study, Gabriel (2003) highlights the improvement in quality of life of the chemotherapy PICC line patients as a result of the reduced need for peripheral venous cannulation.

Again it can be seen that a number of similar themes are discussed in the somewhat limited literature regarding the patient-impact of PICC lines. In keeping with the literature relating to

patient-impact of implanted ports (Borst et al 1992; Bow et al 1999; Chernecky 2001; Goossens et al 2001) and tunnelled CVCs (Claessen et al 1990; Daniels 1996), the reduced need for venepuncture and cannulation as a result of the PICC line being *in situ* is highlighted as a positive aspect (Oakley et al 2000; Gabriel 2000, 2003). There is agreement that despite the difficulties, patients cope well with PICC lines and the impact on daily life is minor, although a limitation of many studies is the lack of data collected specifically addressing this. However, the literature available does appear to suggest that the impact of PICC lines is greater than that of implanted ports and tunnelled CVCs in relation to affect on bathing, dressing and sleeping and that PICC line patients are perhaps more defensive of their devices as reflected in their fears of line damage (Oakley et al 2000). This may be a result of the PICC line being more visible than the implanted port and tunnelled CVC and because the PICC line exits the body from the patient's arm. Furthermore, the challenges in preparing patients for the experience of living with a PICC line or other CVAD are again reflected in the findings that despite the information given to PICC line patients prior to insertion, they still felt unprepared for the resulting experience (Borst et al 1992; Oakley et al 2000; Goossens et al 2001). Further research into how ambulatory chemotherapy PICC line patients adapt to their situation and the best ways to inform and support patients through the experience was recommended (Oakley et al 2000).

The next section extrapolates from the literature relating to patient issues in ambulatory therapy generally since very little literature was available regarding the patient-impact of the MdG regimen.

2.7 Ambulatory chemotherapy

For the purposes of this study, ambulatory chemotherapy refers to the administration of chemotherapy in the patient's home, without on site supervision by a health care professional. A number of papers were retrieved which explored ambulatory chemotherapy although again there was no consistency in the study designs or methodologies employed.

2.7.1 Ambulatory versus hospital chemotherapy

The question of choice in ambulatory or hospital based chemotherapy was the focus of a study carried out in three cancer hospitals in Greece by Christopoulou (1993). A sample of 184 cancer patients receiving chemotherapy were surveyed using a structured questionnaire to examine the biosocial factors which influence a patient's decision to be treated at home or in hospital. No description of the sample method is stated although it appears to be a convenience sample. A number of variables were determined to represent the biosocial factors including gender, family status, disease status, financial status and social factors. Statistical analysis of

the data identified the significant factors in terms of who underwent ambulatory chemotherapy and why patients chose ambulatory chemotherapy, although the statistics are not reported. The most important factors affecting the patient's decision to undertake ambulatory chemotherapy were previous experience with ambulatory therapy and degree of ambulatory services development. Economic and financial variables and patient characteristics such as gender, family status and educational level did not appear to affect the decision of patients as to where they received their chemotherapy.

Christopoulou (1993) found that 98.1% of patients preferred ambulatory chemotherapy but that this preference was dependent upon level of family support at home and the degree of home health care development. Unfortunately Christopoulou does not describe in detail what these home health care developments constitute although one assumes that it refers to the level and extent of service development relating to the provision of ambulatory chemotherapy. Furthermore, the detail provided regarding the issues surrounding patients who underwent ambulatory chemotherapy is scant but nonetheless, the importance of supporting patients undergoing ambulatory chemotherapy was stressed.

The importance of support was also reported by Dougherty, Viner and Young (1998) in a paper discussing the role of the clinical nurse specialist in supporting ambulatory chemotherapy patients. A convenience sample of 100 patients in a UK specialist oncology department completed a questionnaire designed to evaluate the education and support they had received when undergoing ambulatory chemotherapy. Unfortunately little detail is provided regarding the underlying methodology but it was shown that 95% of patients found the experience of ambulatory chemotherapy at home "daunting" despite the education provided being satisfactory. Dougherty et al (1998) also stated that although many patients had a desire to undertake ambulatory chemotherapy, not all patients could cope with this method of delivery and some prefer the security of the hospital setting. In addition, they stated that some patients may be unwilling or mentally/physically unable to take on the responsibility needed and therefore patient selection is crucial, as previously discussed by Cole (1999) and Dobson (2001).

2.7.2 Ambulatory chemotherapy and quality of life

A randomised controlled trial to compare ambulatory versus out-patient chemotherapy in terms of safety, compliance, use of health services, quality of life and satisfaction with treatment was conducted by Borrás, Sanchez-Hernandez, Navarro, Martinez, Mendez, Ponton, Espinas and Germa (2001) in a large Spanish teaching hospital. A questionnaire was developed to gather data on the outcome measures: treatment toxicity, patient's compliance with treatment, quality of life, satisfaction with care and use of health services. The EORTC QLQ-C30, a validated

quality of life tool commonly used in clinical trials in the cancer setting (Aaronson, Ahmedzai, Bergman, Bullinger, Cull, Duez, Filiberti, Flechtner, Fleishman and de Haes 1993), was used to gather the quality of life data. A sample of 87 patients was randomised to receive chemotherapy for colorectal cancer at an out-patient clinic (n=42) or in their own home (n=45). The study found that voluntary withdrawal from chemotherapy was significantly higher in the out-patient group than the ambulatory group (difference 12%, 95% CI, 1% - 24%) but that there were no significant differences in use of health care services (namely unplanned visits), quality of life or satisfaction with health care generally. Although global satisfaction with health care was higher in the ambulatory group, the difference was not statistically significant (difference 8%, 95% CI, 0% - 17%). Despite the lack of significant differences in most of the outcome measures, Borrás et al (2001) concluded that ambulatory chemotherapy could be advantageous for patients mainly by increasing compliance with treatment. Furthermore they postulated that ambulatory chemotherapy seemed an acceptable and safe alternative to out-patient treatment although there was little evidence of improvement on quality of life. The Borrás et al study (2001) was one of the first studies to attempt to evaluate the impact of a change in delivery of chemotherapy (out-patient to ambulatory) on a number of outcome measures and recognised that the impact on patients in terms of satisfaction with care is often neglected. Furthermore, it is important to note that many of the assumptions regarding ambulatory care, for example that it improves patients' quality of life, were not upheld in the study.

More positive findings regarding quality of life with ambulatory chemotherapy were reported by Rowe, Valle, Swindell, Fitzsimmons and James (2002). Rowe et al conducted a pilot study in a UK-based cancer centre to assess the feasibility and patient acceptability of ambulatory administration of the de Gramont chemotherapy regimen normally given as in-patient. Patients who required de Gramont chemotherapy were assessed for suitability for ambulatory administration by a medical team comprising a doctor, research nurse and pharmacist. Those deemed suitable were then given information regarding the administration and side effects of both the in-patient and ambulatory regimens and then chose which regimen they wished to undertake. Twenty six patients were non randomly allocated to receive either standard inpatient (n=13) or novel ambulatory (n=13) chemotherapy. Quality of life was assessed by means of the EORTC QLQ-C30 questionnaire administered at baseline and weeks one, three and six. Further data on perceived benefits of chosen regimen and resulting experiences are also reported although it is not clear which method was used to collect this data.

Rowe et al (2002) found that the novel ambulatory treatment was feasible and highly acceptable to patients. Benefits reported by the ambulatory patients included a perceived increase in independence, a reduction in travel to the hospital, reduction in hospital-related delay and a

reduction in the number of peripheral cannulations required. Patients choosing the in-patient chemotherapy perceived they would feel more secure in hospital, lacked adequate support at home and feared having the CVAD necessary for ambulatory chemotherapy.

In terms of overall health and quality of life, higher scores correlating with improved health or quality of life were seen in the ambulatory arm compared with the in-patient arm although no test of statistical significance was applied. In the ambulatory arm, 75% of patients (numbers not reported) reported an increase in overall health score at 3-6 weeks with 100% of patients reporting either the same or improved quality of life score. This contrasted with the in-patient group where 100% of patients reported a decrease in overall health score, with quality of life either the same or decreased at 3-6 weeks. Rowe et al (2002) concluded that the ambulatory regimen offered considerable quality of life benefits to patients which also led to an increase in patient morale. They acknowledged however a limitation of the study was that since the ambulatory patients were selected on the grounds of both suitability criteria and acceptance of the mode of delivery, the younger and generally fitter patients in the ambulatory arm were likely to have tolerated treatment better than the in-patient group.

Despite the decrease in quality of life and overall health score found in the in-patient group, these patients stated that if they required treatment again in the future, they would again choose the in-patient regimen. In keeping with others (Dobson 2001; Cole 1999; Dougherty et al 1998) Rowe et al (2002) stressed that patient selection for ambulatory chemotherapy is essential and in addition that adequate support in the community and from the hospital are vital. Furthermore, the authors acknowledge that there was considerable support from key members of the health care team in preparing and supporting the 13 patients receiving ambulatory chemotherapy since recruitment averaged only one patient per month into the ambulatory arm. It is feasible that the benefits felt by ambulatory patients were in part due to the intensive support available to patients from both hospital and community-based staff that may not be available out with the clinical trial setting. Rowe et al (2002) further acknowledged the importance of such support for patients undergoing ambulatory chemotherapy but that it is not uniformly available.

2.7.3 Safety and acceptance of ambulatory chemotherapy

The safety and acceptance of ambulatory chemotherapy is a theme prevalent throughout the literature and is discussed in detail by the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) in a report into home-based chemotherapy and the issues for patients, caregivers and the health care system (AETMIS 2004).

AETMIS is a multi-disciplinary agency whose role is to contribute to improving the Quebec health-care system by supporting the Minister of Health and Social Services and health care providers. AETMIS (2004) produced a lengthy report into ambulatory chemotherapy in response to earlier findings of AETMIS which highlighted that ambulatory care was the fastest growing service delivery model found in industrialized nations. No similar report could be found in the literature relating to any UK-based organisation. Furthermore, although a Canadian document, a number of the findings are applicable to patients generally and therefore also to health care in the UK.

2.7.4 Patient preference for ambulatory chemotherapy

AETMIS (2004) reviewed the literature concerning effectiveness, safety, cost implications, patient preference, satisfaction and quality of life in relation to ambulatory chemotherapy from 1975 to 2002 which was supplemented with semi-structured qualitative interviews with ambulatory chemotherapy providers (n=17). Detailed search parameters are provided in the report and demonstrate a comprehensive and substantial review of relevant literature. The findings regarding patients and carers are presented here.

AETMIS (2004) reviewed 11 papers which reported patient preference for and/or satisfaction with ambulatory chemotherapy. A smaller number of studies also specifically addressed quality of life in ambulatory chemotherapy. There was no uniformity in terms of study methodology or design and the papers reviewed comprised a mix of randomised controlled trials (RCTs) (n=5), controlled studies (n=2) and uncontrolled studies (n=7). A variety of patient groups were sampled including adults and children undergoing ambulatory chemotherapy for cancer, making direct comparisons impossible. The studies had varying aims and objectives in relation to exploring patient preference and/or satisfaction with ambulatory chemotherapy but the findings demonstrate common themes.

AETMIS found strong positive evidence favouring ambulatory treatment in nine of the 11 studies reporting on patient preference. In terms of satisfaction, seven of the nine relevant studies showed patients were satisfied with their ambulatory treatment. However two studies failed to show any differences in satisfaction between hospital and ambulatory care. AETMIS highlighted that the positive evidence supporting patient preference for ambulatory therapy is not surprising since for all trials, patients had to meet strict eligibility criteria and to be willing to undertake ambulatory chemotherapy in order to take part in the trial. Thus there may be a bias towards preference in these studies. However it would not be possible to design a trial whereby patients who refused ambulatory therapy were subsequently given it and therefore bias is unavoidable.

A number of reasons for the acceptance or rejection of ambulatory therapy are discussed (AETMIS 2004). Reasons cited for preference for ambulatory chemotherapy included familiarity with the home environment, a reduction in travel to hospital, an increase in control over life and less disruption of family routine. A reduction in satisfaction and/or preference was associated with fear of malfunction of associated technology, lack of supervision when receiving treatment and a restriction or change in daily routine as a result of treatment regimen. It was also noted that some patients did not want to accept the responsibility for their own health care management and preferred that responsibility to lie with a health care professional.

2.7.5 Safety issues in ambulatory chemotherapy

Safety issues surrounding ambulatory chemotherapy were explored in 21 studies reviewed by AETMIS (2004). Again these comprised a mix of RCTs (n=4), controlled studies (n=4) and uncontrolled studies (n=13). Safety issues in relation to the monitoring of side effects, handling of waste and excreta, the use of specialised equipment and the care of children whilst undergoing ambulatory chemotherapy were highlighted as areas of difficulty for both patients and their informal carers, usually relatives, in all studies.

Despite this, AETMIS (2004) concluded that ambulatory chemotherapy could be provided safely and is an option for some cancer patients who choose it. Furthermore, AETMIS found that improvements in quality of life for patients receiving chemotherapy in the ambulatory setting are frequently reported in the literature anecdotally but with little supporting evidence. AETMIS recommended that further research into the views of ambulatory chemotherapy patients and their carers be conducted to evaluate quality of life.

In summary, the findings from AETMIS (2004) are in keeping with those previously discussed and demonstrate that whilst ambulatory chemotherapy is acceptable and safe for many patients (AETMIS 2004; Borrás et al 2001), some patients may be unable or unwilling to take on the responsibility needed (Dougherty et al 1998). Although improvements in quality of life are documented in the literature (Rowe et al 2000), much of the evidence is anecdotal and further research is required to produce a robust evidence base (AETMIS 2004). Ambulatory chemotherapy is not without potential problems and is without doubt a challenge for patients and their carers (AETMIS 2004; Dougherty et al 1998; Herbst 1996). There exists an additional informational burden on ambulatory chemotherapy patients (AETMIS 2004) which is further explored in the next section.

2.8 Information giving to chemotherapy patients

No literature relating specifically to MdG ambulatory PICC-line patients' information needs was identified. Therefore the literature relating to cancer patients' information needs and chemotherapy patients' information needs was reviewed as the MdG PICC-line patients in this study are both cancer and chemotherapy patients.

2.8.1 Perceptions of information need during chemotherapy

Fernsler (1986) carried out a descriptive study looking at the differences in self-care deficits as reported by chemotherapy patients and nurses. Fernsler used a convenience sample of 30 chemotherapy patients and their assigned nurse to carry out open-ended, semi-structured interviews derived from Orem's self-care model of nursing. Fernsler found that patients generally reported more self-care deficits than their nurse although nurses reported more self-care deficits than patients when it came to psychosocial issues: nurses perceived patients as being more anxious, depressed and hostile than the patients themselves did. Fernsler concluded that nurses failed to perceive the extent to which chemotherapy patients require assistance and they were therefore unable to meet the patients' information needs. Although the findings from Fernsler's (1986) study cannot be generalized, the nurses involved provided information they thought patients required to cope but this was not always in keeping with the patient's perceived or actual information need.

2.8.2 Information needs of patients with cancer

Meredith et al (1996) conducted a cross sectional survey of patients' views using a semi-structured interview with questionnaire to assess the needs of patients with cancer for information about their condition. The questionnaire used was used in other studies although no comment is made regarding validity and reliability. Data on overall preference for information and preference for information related to specific aspects of their disease and treatment was collected. A sample of 250 patients from 269 approached (93% response rate) consented to take part in the study. The sample was stratified by age, sex, socioeconomic status and tumour site to be representative of the population of West of Scotland. It was found that most patients wanted as much information as possible about their disease (79%, 95% CI, 73% - 84%), chance of cure (91%, CI, 87% - 94%) and side effects of treatment (94%, CI, 90% - 97%). Furthermore, patients who were younger, female and/or receiving radical treatment demonstrated a greater need for information relating to treatment options. Owing to the sampling method used, Meredith et al suggested that these results were representative of the population of West of Scotland and therefore it appears that the vast majority of patients with cancer wish to receive as much information as possible about their situation. Whilst this finding

is important in alerting health care professionals to the patients' need for information, it is limited in that it sheds no light on how patients cope with the information which may be complex and lengthy.

Similar findings were reported by Graydon, Galloway, Palmer-Wickham, Harrison, Rich-van der Bij, West, Burlcin-Hall and Evans-Boyden (1997) in a study to assess the information needs of women undergoing treatment for breast cancer in a Canadian regional cancer centre. A purposive sample of 70 women receiving chemotherapy (n=25), radiotherapy (n=23) and surgery (n=22) completed the breast cancer version of the Toronto Informational Needs Questionnaire (TINQ-BC). The TINQ-BC was developed from literature review findings and demonstrated content validity and high internal reliability (Cronbach's alpha 0.94) and collects data on the need for information about disease, investigations, treatment, physical care and psychosocial issues such as family concerns. Scores range from 51 to 255 with a higher score indicative of a high information need.

Graydon et al (1997) found that all women had high information needs regardless of treatment type (TINQ-BC range 148 – 253). Analysis of the results by treatment type showed that the highest information needs were reported in women undergoing their first course of chemotherapy (TINQ-BC range 201 – 253; mean 224.9). Interestingly this group contained the women with the lowest average age (40.5 years) and compares with the findings of Meredith et al (1996) reported earlier who found that younger, female patients had a higher need for information relating to treatment options. Furthermore, when sub-divided by information type, the highest information needs were those associated with the disease itself, investigations and treatment with physical and psychosocial information needs scoring lower. Importantly, this high information need persisted as treatment progressed. The authors' state that this may have been a result of either the fear associated with cancer treatment or because the information given at the start of treatment was not understood. As with Meredith et al (1996), Graydon et al's (1997) study does not address the impact of information given, only that information is desired. Graydon et al also recommend further study into how the needs of women undergoing breast cancer treatment could best be met.

2.8.3 Patient satisfaction with chemotherapy information

Sitzia and Wood (1998a) conducted a literature review drawing on three main areas of research in relation to chemotherapy nursing namely oncology nursing care, patients' experiences of ambulatory chemotherapy and patient satisfaction. The search parameters used are not stated but the extensive reference list suggests a thorough evaluation of relevant literature.

The review aimed to provide a broad overview of satisfaction with chemotherapy care as this was an area identified by the authors as lacking an evidence base. Although the difficulties associated with satisfaction studies such as the subjective nature of satisfaction and the tenuous link between perceived satisfaction with care and actual care provided are recognized, Sitzia and Wood (1998a) state that good information giving is vital to satisfaction with chemotherapy care, both of which are linked to compliance with treatment. This is interesting to note as Borrás et al (2001) (section 2.7) also found that home chemotherapy could be advantageous for patients mainly by increasing compliance with treatment and satisfaction with nursing care. Thus it appears there may be a link between information giving, ambulatory chemotherapy, compliance with treatment and satisfaction with care. Sitzia and Wood (1998a) also found that the provision of information to patients undergoing chemotherapy was an important determinant in alleviating distress and impacting positively on quality of life. However, the literature was inconclusive regarding the reasons for dissatisfaction with chemotherapy information. Whilst some studies reported a lack of information given to patients, others found poor recall of information given to be the reason for reported dissatisfaction. It would appear therefore that whilst patients desire information (Meredith et al 1996, Graydon et al 1997) they may not remember it and therefore information giving to chemotherapy patients continues to be perceived as generally poor (Sitzia and Wood 1998a).

Following their literature review Sitzia and Wood (1998b) went on to explore satisfaction with chemotherapy nursing care using the Worthing Chemotherapy Satisfaction Questionnaire (WCSQ). The WCSQ is a self-report questionnaire which collects both qualitative and quantitative data and which has been shown to display reasonable reliability and validity (Sitzia and Wood 1998b). The study was aimed at ambulatory chemotherapy patients, although it is not clear whether any of the patients required a particular CVAD in order to receive their treatment. A convenience sample of 173 patients completed the questionnaire. The findings from the later study (Sitzia and Wood, 1998b) confirmed the findings from the earlier literature review (Sitzia and Wood 1998a). It was discovered that overall satisfaction with chemotherapy-related nursing care was high but that dissatisfaction existed with the provision of information. Sitzia and Wood (1998b) postulated that this may be partly because of the relative unpredictability of chemotherapy and the lack of evidence based literature regarding regimen-specific side effects. Aspects of chemotherapy related information are therefore sometimes necessarily vague and patients can only be informed of what is likely to happen rather than what will definitely happen or not.

Also in keeping with the literature review findings (Sitzia and Wood 1998a), Sitzia and Wood (1998b) found an association between satisfaction and compliance. Patients who were non-

compliant with the chemotherapy regimen were generally less satisfied with chemotherapy care and with all aspects of patient information. A further finding was that patients wanted different types and levels of information and thus information giving in this particular group of patients was complicated. Furthermore, ambulatory patients in particular wanted both emotional support and practical information regarding coping at home but were not given information they needed to cope with life during chemotherapy. It may be therefore that chemotherapy patients are being given information but it is not perceived by them to be the information they require, as reported by Fernsler (1986).

2.8.4 Information needs of chemotherapy patients

Knowles, Tierney, Jodrell and Cull (1999) assessed the information needs of patients receiving chemotherapy for colorectal cancer at a regional cancer centre in Edinburgh and reported positive and negative findings. All new patients (n=80) attending the centre for consideration of chemotherapy for surgically-resected colon cancer were recruited into the study. All patients who subsequently received chemotherapy (n=40) consented to take part in the study. A mixed-methods approach was taken whereby patients completed three information needs questionnaires, the State-Trait Anxiety Inventory (STAI), a quality of life questionnaire (EORTC QLQ-C30) and a semi-structured interview before, during and after their course of chemotherapy.

Knowles et al (1999) found that patients had both positive and negative perceptions of the information given to them regarding their chemotherapy. Although 97% (n=34) of patients reported appreciation at being given clear and honest information prior to chemotherapy, 68% (n=24) reported difficulty coping with the information, 51% (n=18) felt insufficient information had been given and 46% (n=16) reported "information dilemmas". This dilemma stemmed from being asked to make a decision about treatment options in that patients on the whole wanted the specialist to decide what treatment was best for them. Knowles et al's (1999) study serves to confirm Sitzia and Wood's (1998b) conclusion that information giving in patients diagnosed with cancer and undergoing chemotherapy is complex and challenging. This is not unexpected since patients are faced not only with a life threatening diagnosis, but also lengthy and complex treatment regimens that are unfamiliar to them.

A later study which also specifically focussed on the information needs of cancer patients receiving chemotherapy in Northern Ireland was carried out by McCaughan and Thompson (2000). The aim of their study was to identify the needs of day case chemotherapy patients at the beginning, middle and end of their treatment. A questionnaire which collected both quantitative and qualitative data was completed by a convenience sample of 42 patients from 72

approached (56% response rate). The data were analyzed with respect to information needs, information received, appropriateness of information and overall satisfaction with information. Overall satisfaction with information received was high with 92.5% of patients stating that the information they had received had been "about right". In keeping with Meredith et al (1996) and Graydon et al (1997), McCaughan and Thompson (2000) found that most patients (84.2%) wanted as much information as possible but that many patients failed to retain much of the vast amount of information associated with chemotherapy treatment, a key finding from Knowles et al (1999). Like Sitzia and Wood (1998b), McCaughan and Thompson found that patients wanted information about factors related to their "out-patient" status including practical advice and maintaining normal family relationships but this was not provided. Limitations of the study were highlighted as being the low response rate and the fact that it was patients' perceptions of information received rather than actual information received that was measured. However, Sitzia and Wood (1998b) state that cancer patients' perceptions of health status can influence behaviour more than actual health status thus it could be argued that perceptions of the information "experience" are a legitimate and justifiable area of enquiry.

More positive findings regarding information giving to patients undergoing chemotherapy were reported by Elf and Wikblad (2001) who investigated satisfaction with information and quality of life in patients undergoing chemotherapy in a Swedish county hospital. A convenience sample of 30 patients receiving chemotherapy for a variety of cancers was interviewed and also completed the Miller Behavioural Style Scale (MBSS) and the EORTC QLQ-C30 quality of life tool. The interviews were semi-structured and questioned patients on the information they perceived as important, their satisfaction with information received and whether they perceived that they needed more information in relation to chemotherapy. The MBSS was used to differentiate between information seekers ("monitors") and information avoiders ("blunters"). Elf and Wikblad (2001) found that most of the patients ($n=21$) were satisfied with the information received but that no significant difference existed in quality of life score between those satisfied with information and those dissatisfied (statistics not provided). Of the nine patients dissatisfied with information, eight were female and of younger age, although the age difference was not significant (47 ± 12.6 years vs 55.3 ± 11.9 years). Nonetheless this is interesting as previous studies (Graydon et al 1997; Meredith et al 1996) showed that younger, female patients tend to have the highest information need. Thus the dissatisfaction found in younger, female patients in Elf and Wikblad's (2001) study may reflect this high information need not being met.

The limited sample size and heterogeneous patient group sampled mean that the findings from Elf and Wikblad's (2001) study cannot be generalized to the wider chemotherapy population.

Furthermore the quality of life measurement was taken only once during chemotherapy and therefore may not accurately reflect overall quality of life during chemotherapy which has been shown to vary during treatment (Bow et al 1999). Elf and Wikblad's study does however show that individual patient preference for chemotherapy information may influence satisfaction with information more than actual information received.

2.8.5 Patient dissatisfaction with chemotherapy information

Skalla, Bakitas, Furstenberg, Ables and Henderson (2004) conducted a study in a regional rural academic medical centre in New England, USA to determine patient preferences in relation to need for information about treatment for cancer and side effects. A convenience sample of 51 patients and 14 spouses of patients who had either recently undergone or were undergoing chemotherapy or radiotherapy took part in focus groups. Patients who were considered to be "too ill" (no criteria given), those experiencing cognitive difficulties and the hearing-impaired were excluded from the study. Facilitator guideline questions were developed in conjunction with the study authors and six haematology/oncology advanced nurse practitioners to reflect appropriate content. The focus groups were led by facilitators trained in group facilitation skills and were audio-taped for later transcription and analysis.

Skalla et al (2004) found that patients were generally dissatisfied with the information they received. It was reported that although patients wanted information specific to the administration and impact of treatment, much of the information received was useless or not appropriate and that as patients, they felt ill-prepared to cope with the treatment and side effects. Furthermore in keeping with McCaughan and Thompson (2000) patients also stated that the information received was overwhelming and some could actually be described as "destructive". Skalla et al (2004) concluded that patients wanted more specific information relating to how treatment would affect daily life and interestingly state that this may be because much more anti-cancer treatment is now administered out with the in-patient setting, a similar finding to that of McCaughan and Thompson (2000) and Sitzia and Wood (1998b). Thus it can be seen that patients require information to help them adjust to and cope with chemotherapy in the ambulatory setting.

Despite this and the importance placed on communicating with people with cancer, it would appear that health care professionals continue to fail to meet the needs of patients in this area (Kruijver, Kerkstra, Bensing and van de Wiel 2000; Jarrett and Payne 1995; Wilkinson 1991). Furthermore anecdotal evidence from the UK nursing press suggests that the majority of chemotherapy administration and PICC-line services are now nurse-led and under the remit of specialist nurses. Informational support is an essential component of nursing care yet

chemotherapy patients remain generally dissatisfied with the information given to them on essential aspects of their care (Skalla et al 2004; Sitzia and Wood 1998b). This may be a result of the variation in information desired by patients (Elf and Wikblad 2001) and that provided by nurses, which could reduce effectiveness of interventions (Sitzia and Wood 1998b; Graydon et al 1997; Fernster 1986). Other difficulties in giving information to cancer chemotherapy patients include the fear of cancer that exists in both patients and nurses (Flanagan and Holmes 2000; Box and Anderson 1997); the volume and nature of information that can surround a cancer diagnosis and subsequent treatment pathway (Skalla et al 2004) and the general uncertainty that exists for patients which may cause them to avoid or ignore information given to them (Leydon, Boulton, Moynihan, Jones, Mossman, Boudioni, and McPherson 2000).

2.9 Summary of the literature review

This literature review aimed to explore the impact of a PICC line on patients requiring Modified de Gramont (MdG) chemotherapy in the ambulatory setting. Since no existing literature could be found which specifically addressed this, it was necessary to extrapolate from the wider literature relating to central venous access devices (CVADs) and ambulatory therapy generally.

The literature review demonstrated that little research regarding the impact of a PICC line on the patient receiving ambulatory MdG chemotherapy is available. There exists a modest amount of research related to the patient-impact of other types of CVAD but there is no uniformity in the type of study conducted nor are there any generalizable findings that can be applied to the patients in this study. Furthermore, the findings of the available studies are somewhat contradictory and no definite conclusions can be drawn given their size and scope.

In reviewing the literature, it is clear that there is a wide body of research relating to the technical/medical aspects of PICC lines. However, although the limited research available suggests that PICC lines are generally well accepted by patients (Gabriel 2003, 2000; Oakley et al 2000), there is a lack of evidence-based research into the impact PICC lines have on patients undergoing ambulatory chemotherapy. One of the main reasons for the increase in PICC line usage in the oncology setting has been to facilitate the move towards ambulatory chemotherapy which itself is laden with challenges (AETMIS 2004). Furthermore, throughout the literature there appears to be an assumption that ambulatory chemotherapy benefits patients but there is little attention paid to the additional burdens placed upon them. Despite the rhetoric it would appear that the patient's perspective is largely neglected. If no such evidence exists then arguably nurses will be unable to prepare patients adequately for the experience.

Since there was little research relating to the impact of a PICC line on the patient receiving ambulatory MdG chemotherapy, it was the aim of this study to examine the views and experiences of patients receiving ambulatory MdG chemotherapy via a PICC line in order to contribute to the current understanding and research on the subject matter.

CHAPTER THREE – LITERATURE PERTAINING TO THE METHODS

3.1 Introduction

The aim of this study was to examine the views and experiences of patients receiving ambulatory MdG chemotherapy via a PICC line. The objectives of the study were:

1. To determine which aspects of living with a PICC line cause patients most difficulty.
2. To explore patients' views of the PICC line experience.
3. To determine if patients view PICC lines as a benefit or a burden when receiving ambulatory MdG chemotherapy.

To address the study objectives, a multi-method triangulated study was designed resulting in a two-phase descriptive study employing both qualitative and quantitative methods. Phase 1 of the study involved the collection of qualitative data through semi-structured interviews. These data contributed to the development of a questionnaire to collect quantitative data in Phase 2 of the study to meet the research aims.

Justification of the research approach taken, review of the literature surrounding the methods employed, discussion the concepts of reliability and validity and exploration of the ethical issues raised by this study are presented in this chapter.

3.2 Justification of the research approach taken in this study

3.2.1 Introduction

Nursing research is carried out within two broad paradigms; qualitative and quantitative, and their associated research methods (Polit, Beck and Hungler 2001). Qualitative and quantitative approaches differ ontologically, epistemologically and methodologically (Bryman 2004; Polit et al 2001; Parahoo 1997). Qualitative researchers aim to uncover meaning rather than generalise to the wider population (Polit et al 2001) whereas quantitative researchers aim to make generalisations to the wider population (Bryman 2004). It can therefore be postulated that the qualitative approach is more suited to gathering information on areas of new enquiry with the quantitative approach more appropriate to the further examination of previously uncovered information regarding a phenomenon and hypotheses testing (Bryman 2004; Parahoo 1997).

The literature review for this study demonstrated that both approaches had been employed in previous research in relation to PICC lines with the qualitative approach apparent in studies relating to patient aspects (Gabriel 2003; Oakley et al 2000) and the quantitative approach

common in studies investigating the technical aspects of the lines (Moureau et al 2002; Walshe et al 2002; Cardella et al 1992).

Corner (1991), commenting on the qualitative-quantitative debate, argued that the most appropriate approach is that which meets the overall aims of the research. This study aimed to examine the views and experiences of patients receiving ambulatory MdG chemotherapy via a PICC line. The research objectives sought to explore, describe and measure certain aspects of the experience therefore both approaches were utilised in this study.

3.2.2 Triangulation

The term triangulation can be traced back to navigational, military and surveying contexts (Murphy et al 1998) whereby it was used to pinpoint an exact location by using more than one reference point, rather like the co-ordinates of a map. Murphy et al (1998) cite Campbell and Fiske (1959) as being among the first to introduce the concept into social research although it is noted to refer only to the use of more than one method to test an existing hypothesis.

Denzin (1970) extended the concept of triangulation to include four types; method, data, investigator and theoretical. Method triangulation involves the use of different methods to address the same phenomenon; data triangulation uses different data sources; different investigators are used in the same study with investigator triangulation and theoretical triangulation involves different theoretical models utilised in the same study. It has been argued that triangulation is increasing in popularity owing to the more moderate views of researchers in general, and the recognition that the utilization of triangulation can increase the researcher's likelihood of meeting the aims of the research (Bryman 2004; Foss and Ellefson 2002 and Coyle and Williams 2000).

Debate regarding the strengths and limitations of triangulation exists throughout the literature. Begley (1996) argued that the research methods employed should depend on the research aims but when used appropriately the main advantage of triangulation was to confirm or complete the data. Parahoo (1997) states that although combining different methods in the same study can result in conflicting data, it is the responsibility of the researcher to deal with this and develop understanding of what exactly is going on. Shih (1998) suggested that the qualitative approach could be seen as discovery whilst a quantitative aspect could provide verification of the findings but warned against a mixed approach being seen as "inherently good". Murphy et al (1998) discuss in detail the ways in which triangulation can enhance the validity of research but state that the strongest argument for triangulation is as a means increasing the comprehensiveness of the study. The argument is that triangulation is more likely to demonstrate variations in the

phenomena under study that can be more fully explored and thus add to the truth-value of the research. Some researchers however remain committed to the belief that the triangulation is fundamentally wrong because qualitative and quantitative approaches are epistemologically and ontologically incompatible, as discussed in Bryman (2004) although this rigidity is not apparent in the conventional nursing literature.

One of the most widely accepted uses of triangulation is to develop quantitative measurement tools from data obtained from qualitative interviews (Bryman 2004; Polit et al 2001; Parahoo 1997), a process known as across methods or between methods triangulation (Begley 1996). Oppenheim (1992) whilst not actually using the term triangulation describes the process of carrying out in-depth interviews to generate data for later questionnaire design. This type of design can be seen in the nursing literature; for example Meredith and Wood's (1996) frequently cited study into patient satisfaction with surgical services.

Whilst triangulation cannot be considered a panacea for the difficulties encountered in nursing research, when used appropriately and provided the researcher continually reflects on the processes involved, it can improve the quality and robustness of the research (Bryman 2004; Polit et al 2001; Parahoo 1997). In this study, method triangulation was used to increase study robustness and involved the use of both qualitative semi-structured interviews and quantitative questionnaires. This approach was appropriate because the researcher aimed to both qualify and quantify aspects of the patient-impact of PICC lines. It was also intended that the results would be transferable to the wider MdG PICC line patient population in order that nurses involved in PICC-line services would be better placed to support patients during the experience of living with a PICC line whilst undergoing ambulatory MdG chemotherapy.

The literature review demonstrated that no pre-existing evidence regarding the impact of PICC lines on patients undergoing ambulatory MdG chemotherapy existed. To meet the study aims and objectives it was thus necessary to explore patients' views regarding the PICC-line experience through the qualitative approach but also to quantify which aspects of living with a PICC line caused patients the most difficulty through quantitative methods. Thus the qualitative data collected in Phase 1 of the study were used to develop the questionnaire for use in Phase 2.

3.3 Justification of qualitative methods chosen

3.3.1 Introduction

Different methods of qualitative research exist including interviews, focus groups, observational techniques and diary keeping (Bryman 2004). In this study focus groups were rejected owing to the limited time and resources available and researcher inexperience. Observational studies were inappropriate since it would not have been possible to observe patients going about their daily lives. Diary keeping was rejected on the grounds that it could have been too demanding of this group of patients. The method chosen for Phase 1 of the study was the semi-structured interview. This was because the aim was to collect focused qualitative data which would help inform questionnaire development.

3.3.2 Interviews

The interview is the most common method of data collection used in qualitative research (Bryman 2004; Holloway and Wheeler 2002). Parahoo (1997, p 282) describes an interview as "a verbal interaction between one or more researcher and one or more participant for the purpose of collecting valid and reliable data to answer particular research questions".

The main difference between interviews in qualitative and quantitative research is the level of structure applied. Quantitative interviews are highly structured to collect predetermined responses that can be coded easily whereas qualitative interviews are loosely structured (although to varying degrees) and allow the researcher flexibility in data collection (Bryman 2004; Holloway and Wheeler 2002; Clifford 1997).

Bryman (2004) states that semi-structured interviews are applicable when the researcher has identified specific areas of interest in relation to the subject matter. Semi-structured interviews were thus appropriate for this study since the aim was to collect qualitative data in relation to the patient-impact of a PICC line.

Semi-structured interviews have a focus in terms of the types of data to be collected but allow the researcher flexibility in terms of the wording and sequencing of questions (Holloway and Wheeler 2002; Clifford 1997) and allow the interviewer to seek clarification of findings at the time (Parahoo 1997). An 'interview guide' which contains questions pertinent to the areas of interest is used (Bryman 2004; Holloway and Wheeler 2002; Polit et al 2001) and allows the researcher to capture the world through the eyes of the participants but also ensures that the data collected are comparable for the purposes of seeking patterns (Parahoo 1997) and generating ideas (Bryman 2004).

Strengths of semi-structured interviews include the high response rates obtained (Polit et al 2001; Parahoo 1997); that they are very participant orientated (Clifford 1997); that they allow clarification of responses and are good for new areas of study (Bryman 2004). Limitations include potential interviewer bias and the propensity of collecting useless data (Parahoo 1997). Furthermore they are very labour intensive (Pontin 2000), and arguably are unable to truly capture the participants' real world (Bryman 2004).

3.3.3 The role of the researcher in qualitative research

The qualitative approach dictates that the researcher is viewed as having influence over all aspects of the research process (Parahoo 1997) but it remains important that qualitative researchers aim to minimise error (Pellatt 2003; Murphy et al 1998). The use of reflexivity is one way in which qualitative researchers have attempted to answer their critics with regard to the issue of subjectivity (Bryman 2004).

Many definitions of reflexivity exist (Carolan 2003; Pellatt 2003) but there is consensus that it is a process whereby the researcher continually reflects upon the ways in which he or she may have influenced the research process (Parahoo 1997). This may be in terms of the approach taken, study design employed, analysis of data or in the actual interaction of the researcher with the research participants (Bryman 2004; Murphy et al 1998).

The researcher must thus continually reflect upon the impact of his/her thoughts, assumptions and attitudes as well as actual presence are having on the research process and present evidence of decision-making processes (Holloway and Wheeler 2002). Provided a full explanation is given through a reflexive account, the researcher's existing knowledge and experiences may add value to the study by providing thoughtful insight into the findings and by further developing theory (Hand 2003; Porter 2000). The researcher employed reflexivity throughout the study.

3.3.4 Qualitative data analysis

Content analysis has been used in both qualitative and quantitative research (Bryman 2004; Cavanagh 1997) and is described by Polit et al (2001) as a process whereby qualitative data are organized according to emerging themes and concepts which can then be quantitatively measured. This involves studying texts, analysing the words and grouping them into a smaller number of content related categories (Cavanagh 1997). Fuller explanation of the steps taken is provided by several writers (Polit et al 2001; Cavanagh 1997; Burnard 1991) namely immersion in the data, consideration of 'a priori' information, category definition, initial coding, revised coding and data analysis. It is suggested that using expert peer review and/or looking for

consistency between more than one coder makes the process more reliable (Polit et al 2001; Cavanagh 1997).

Manifest content analysis refers to the process of discovering 'what is said' as opposed to 'why it is said' (Polit et al 2001) in keeping with the original work by Berelson (Cavanagh 1997). Thus manifest content analysis was employed for the analysis of the qualitative data collected in Phase 1 of this study since the researcher was looking for common themes rather than attempting to interpret the meaning of what was said, a process more commonly associated with particular research traditions such as phenomenology and grounded theory (Polit et al 2001).

3.4 Justification of quantitative methods chosen

3.4.1 Introduction

Three main quantitative research designs were identified in the literature: descriptive, correlational and experimental (Polit et al 2001; Carter 2000; Parahoo 1997). In this study there was not enough pre-existing information regarding the impact of a PICC line on the patient receiving MdG chemotherapy to allow the researcher to isolate any specific variables for investigation and therefore experimental and correlational designs were unsuitable.

A descriptive design was the most appropriate to address the aims of the study. Structured interviews, structured observations and questionnaires were considered. Structured interviews were rejected on the basis of limited time and resources. Structured observations were rejected on the grounds that it would not have been possible to observe patients going about their daily lives. As the researcher knew in advance the type of information she was seeking given the literature review and interview data, a questionnaire was most appropriate.

3.4.2 Questionnaires

Questionnaires are the most widely used data collection instrument (Bryman 2004; Polit, Beck and Hungler 2002; Parahoo 1997; Oppenheim 1992). Parahoo (1997, p247) defines a questionnaire as "a method that seeks written or verbal responses from people to a written or verbal set of questions or statements". Questionnaires can be administered by a researcher or completed by participants themselves and vary in terms of their structure, obtrusiveness, objectivity and quantifiability (Polit et al 2001). They can be used to describe, evaluate and measure aspects of the phenomenon under investigation (Parahoo 1997).

The self-report questionnaire is the most commonly used in health and social research (Bryman 2004). Structured self-report questionnaires are appropriate when the researcher knows in

advance the type of information they require to address the study objectives (Polit et al 2001). It can be completed in the absence of the researcher and contains a number of pre-coded questions or statements that respondents reply to (Polit et al 2001; Oppenheim 1992).

Strengths of questionnaires include the relative ease of distribution and data analysis (Oppenheim 1992); the high level of relevant data obtained about different aspects of the phenomenon under study (Murphy-Black 2000; Parahoo 1997); the convenience afforded to participants (Bryman 2004); and the reduction or absence of interviewer bias (Bryman 2004). Limitations include potential low response rates (Oppenheim 1992); response biases (Polit et al 2001); the inability to seek clarification of responses (Bryman 2004) and the superficial view of phenomenon obtained (Bryman 2004). Despite the limitations, Parahoo (1997) states that when used in descriptive studies, questionnaires can provide data that expand and improve understanding of the phenomenon, aid further conceptualisation and lead hypothesis development.

Questionnaires can be designed to collect data on the experiences, attitudes and opinions of patients (Duxbury and Senior 2003; Polit et al 2001; Oppenheim 1992) and are commonly used by nurse researchers (Priest, McColl, Lois, and Bond 1995). Oppenheim (1992) distinguishes between factual data such as age, gender and eye colour for which a precise answer exists and non-factual data such as attitudes, beliefs and views which are more likely to be multi-faceted and thus may be more difficult to assess. Polit et al (2001, p271) refer to "composite scales" which allow the researcher to explore, describe and measure such multi-faceted concepts. These scales comprise a number of statements or items that express a viewpoint on a particular subject. Respondents are asked to rate the statement in some way allowing the researcher to categorize respondents according to strength of view or opinion held (Polit et al 2001; Oppenheim 1992). The main advantage of using a scale to assess experiences or viewpoints is that they can explore different aspects of the opinion or viewpoint which could not be disclosed by responding to a single question (Adams 1998). Since this study was concerned with patients' views regarding the impact of a PICC line, it was necessary for the questionnaire to contain a composite scale.

The most common types of scaling technique are the Thurstone, Guttman, semantic-differential and the Likert scale (Edelmann 2000). All scales have their strengths and limitations and the scale chosen should best suit the aims and resources of the study (Edelmann 2000; Oppenheim 1992). The Likert-type scale was chosen as the most appropriate method of assessing patients' views as it is useful in descriptive studies (Oppenheim 1992) and is regarded

as being less time-consuming and more straightforward in terms of development and completion than other rating scales (Polit et al 2001; Edelman 2000).

3.4.3 Likert Scales

The Likert scale is a multiple-indicator or item measure of opinion held towards an area of interest (Bryman 2004; Oppenheim 1992). The items included must be statements rather than questions and must all relate to the same area of interest (Bryman 2004). Furthermore the scale must exhibit homogeneity, that is, all the items must be internally cohesive (Oppenheim 1992).

Participants are asked to indicate their level of agreement or disagreement to a number of statements which are then collated to provide an indication of the strength of opinion held (Polit et al 2001). Debate exists as to the optimal number of positions offered on the scale and also the usefulness of a neutral position (Oppenheim 1992; Edelman 2000) although ultimately the basic aim of the scale remains the same (Adams 1998). The most commonly used Likert-type scales consist of five categories of response usually ranging from strongly agree to strongly disagree (Jamieson 2004; Edelman 2000; Oppenheim 1992). It is suggested that the inclusion or exclusion of a neutral point be decided on the basis of whether a neutral point is sensible and acceptable (Priest et al 1995; Oppenheim 1992). Likert-type scales also allow for the inclusion of less obvious items which the researcher believes may be linked to opinions and can help develop underlying theory regarding the phenomenon under study (Oppenheim 1992).

The main criticism of Likert-type scales is that they are technically irreproducible (Oppenheim 1992). Because the structure is such that the total score for any participant can be gained in a number of ways, identical scores may be obtained for multiple participants with different underlying meanings (Edelman 2000). As with other composite scales, Likert-type scales can also be affected by response set biases, namely social desirability bias, extreme response bias and acquiescence response bias (Polit et al 2001). The responses may therefore reflect underlying personality traits of the participants rather than the actual attitude or opinion held.

A further limitation of Likert-type scales is that they do not allow the researcher to determine when an opinion towards an item changes from mildly positive to mildly negative and the neutral point, if included can be difficult to interpret (Oppenheim 1992). However, provided all limitations are taken into account during data analysis, Likert-type scales have been shown to perform well in social and health research and can also produce ideas for future research (Oppenheim 1992).

3.4.4 Quantitative data analysis

Quantitative data are numerical (Bryman 2004; Polit et al 2001) and analysis involves organising data to be presented in a meaningful way (Parahoo 1997). Data analysis in quantitative research is dependent upon the types of variable under investigation (Bryman 2004). A variable is any item or observation that varies from individual to individual or from time to time (Crichton 2001). In this study, the variables were the responses to the questionnaire statements. The data collected were nominal and ordinal.

Nominal

This is the lowest level of measurement (Polit et al 2001; Parahoo 1997; Heiman 1996). Nominal data are categorical and are more a method of identification than an actual measure of amount (Heiman 1996). Thus nominal scales assign respondents into ordered categories which have no hierarchical ranking (Belcher 2001). For example, blue eyes are not greater or lesser than green eyes. The demographic data collected in this study were thus nominal.

Ordinal

Ordinal scales are similar to nominal scales but constitute a higher level of measurement as the values can be ordered or ranked (Belcher 2001). However the value is a relative amount rather than a true measurement in the mathematical sense (Polit et al 2001; Heiman 1996). This is because the value attached to the variable is used only to reflect increasing or decreasing value and there is no equal unit of measurement between the scores (Heiman 1996). For example, the difference between a mild, moderate and severe pain score cannot be measured in any way however severe pain is worse than mild pain. Likert-type scales thus collect ordinal data which is ranked according to how much participants agree or disagree with the given item statements (Bryman 2004; Polit et al 2001; Belcher 2001). The data generated from the Likert-type scale used in the questionnaire in this study were therefore ordinal.

A further consideration in quantitative data analysis is whether the variables are measured on a continuous or discrete scale; that is to say, whether or not the measurements can sensibly include a decimal point (Heiman 1996). Nominal and ordinal data are discrete (Belcher 2001; Heiman 1996) thus the data collected in this study were discrete. The presence of discrete or continuous variables and the level of measurement involved determine which statistical procedures may be applied to the data (Belcher 2001; Crichton 2001; Heiman 1996). The resulting analysis produces either descriptive or inferential statistics (Crichton 2001; Polit et al 2001; Heiman 1996).

Descriptive statistics are used to organise and describe data (Polit et al 2001) in order that important characteristics of the data can be easily displayed (Heiman 1996). Descriptive statistics provide a summary of the data for a particular variable using tables and graphical representations such as bar charts and (Crichton 2001). However, it is important to note that descriptive statistics only describe the characteristics of the sample used in the study (Polit et al 2001; Heiman 1996) and if the researcher wishes to generalise from the sample to the population, inferential statistics are necessary (Polit et al 2001; Crichton 2001; Heiman 1996).

Inferential statistics use certain mathematical techniques based on ideas of probability to make inferences about the population represented by the sample, from the sample data obtained (Polit et al 2002; Heiman 1996). Hypothesis testing and estimation through confidence intervals are the most commonly used inferential statistics in health-related research (Crichton 2001). It is strongly argued that confidence intervals are more useful than hypothesis testing as they provide not only a measure of statistical significance (or not) but also provide information on the size of the observed effect (Crichton 2001; Davies 2001). This means that researchers can tell whether the effect is statistically significant and also judge whether any effect is clinically relevant (Crichton 2001; Davies 2001).

The confidence interval provides a range of values that the population mean or proportion is likely to lie within (Crichton 2001). Thus it is an estimate of the true but unknown effect size with an upper and lower limit on the probable size of the effect (Davies 2001). A proportion usually between 90 and 99% will also be specified known as the confidence level with the upper and lower limits known as the confidence limits (Davies 2001). The 95% confidence level is most commonly utilised (Crichton 2001; Davies 2001) which means that the true value of the variable of interest will lie within the confidence limits 95% of the times that the method is used.

Statistical significance is assessed from a confidence interval depending on whether or not the confidence interval contains the value reflecting 'no effect' (Davies 2001). Thus if a confidence interval contains the value zero, then the result is not statistically significant. The confidence limits also provide information on the width of the confidence interval (Crichton 2001). The wider the confidence interval, the greater the margin of error and hence the less precise the information about the size of the effect (Crichton 2001). A narrower confidence interval suggests either small variability of the variable under investigation or a large sample size and therefore a more precise estimate of the true effect (Davies 2001).

However statistical significance does not infer clinical significance therefore one must take care in the interpretation of confidence intervals (Crichton 2001; Davies 2001). Davies (2001) further states that the size of the effect must be considered in light of the significance. For example, a clinical trial may show that a new drug lowers blood pressure more than the existing drug and the difference is statistically significant. However, the effect may be so small that changing the patient's medication is not justified as the clinical benefit is negligible.

It is also important to consider the results in light of the overall study design (Davies 2001). No statistical test is infallible and the only known results are those which apply to the sample (Davies 2001). Thus it is necessary to consider the results with respect to the overall trustworthiness of the study (Davies 2001). This involves consideration of the study design, any possible biases, the sample used and the interpretation of the results (Davies 2001) therefore confidence intervals whilst providing important information do not sit in isolation when interpreting and discussing results.

In this study, both descriptive statistics and inferential statistics were used in accordance with advice from a statistician. Confidence intervals were used as they provided an estimate of the true population proportions that were likely to hold a particular viewpoint and also information on the size of the effect observed.

3.5 Literature relating to validity and reliability

Bryman (2004) states the three most common criteria for evaluating research are reliability, replicability and validity. Validity and reliability are the two crucial elements of assessing the credibility and quality of questionnaires generally and Likert scales specifically (Bryman 2004; Polit et al 2001; Carter and Porter 2000; Parahoo 1997; Oppenheim 1992).

3.5.1 Validity

Validity is the extent to which a data collection instrument measures what it intends to measure (Carter and Porter 2000; Oppenheim 1992). Different types of validity exist but not all may be evident in any given instrument (Eby 1993).

Content validity is concerned with how much the items in the instrument adequately cover the area of interest (Gibbon 1998; Parahoo 1997). Researchers use the literature review, expert opinion and qualitative data from other sources to assert content validity (Gibbon 1998; Oppenheim 1992). Face validity is said to be the weakest form of validity and is simply how much a tool looks like it is measuring what it claims to measure (Polit et al 2001).

Concurrent validity, sometimes referred to as criterion-related validity, is the extent to which a measure correlates with a pre-existing accepted measure, or a previously validated tool (Carter and Porter 2000). Convergent validity is the degree to which different methods of measuring a concept correlate with one another (Bryman 2004). Construct validity examines the relationship between the measure and some potential underpinning theory (Carter and Porter 2000). External validity is the extent to which the instrument of collection would generate the same findings in a setting different to that from which the sample came (Polit et al 2001).

3.5.2 Reliability

Reliability refers to the consistency of an instrument and is a measure of how well the instrument produces the same or similar results if administered under the same or similar conditions (Parahoo 1997). Oppenheim (1992) refers to this in terms of the degree of error of the instrument and explains that high reliability assures us it is the instrument that is producing the results and not a chance finding.

Difficulties exist in determining the reliability and validity of composite scales such as Likert-types scales (Oppenheim 1992). Since attitudes and opinions are indirect indicators of the concept under investigation and are unable to be truly confirmed (Bryman 2004), it is not always possible to measure them against any pre-existing established criteria. Oppenheim (1992) also states that attitudes are complex and context bound and therefore there is no “true” answer to the questions posed. For these reasons, Bryman (2004) states that many researchers are unable to rigorously apply all the principles of validity and reliability in any given study. Furthermore, Oppenheim (1992) states that the purpose of the instrument is the most important consideration and researchers must recognise the limitations inherent in them when making claims from results.

3.5.3 Validity and reliability in qualitative research

Lincoln and Guba (1985) propose a completely new set of criteria for assessing the quality of qualitative research. They rejected the notion of internal and external validity in particular because in their view there is no one true reality and therefore there can be no claim to ever completely accurately represent someone else’s reality through the research process. Instead, Lincoln and Guba (1985) favoured the concept of ‘trustworthiness’ in qualitative research which has four main criteria.

Credibility is used in place of internal validity and refers to the level of agreement between the researchers’ findings and the participants’ realities. Ways of increasing credibility include member checking, peer review, analysis of negative cases and prolonged engagement in the

field. Dependability is similar to reliability and involves the use of an 'audit trail' to ensure that the researcher's processes are logical, traceable and acknowledged. Confirmability is suggested in place of objectivity and is the researcher's way of showing neutrality, which can also involve the use of an audit trail which clearly links the findings and interpretations to the original data sources. Transferability is in place of generalizability where the researcher uses thick description to present the findings in such a way that others can determine if it is relevant to their setting. In addition, Lincoln and Guba propose a number of further steps to be taken to demonstrate the authenticity of the research in terms of the wider impact although Bryman (2004) states that these have not been widely influential in the qualitative research community.

Mays and Pope (2000) however take the viewpoint that the criteria of validity and reliability can be used to evaluate qualitative research provided they are modified to meet the aims of the study in question. They state that the aim of both qualitative and quantitative researchers should be to uncover the "subtle realism" of the world and those in it – that is to discover reality rather than one universal 'truth'. Thus they propose that it is the validity and relevance of the research that is most important as a means of ensuring its quality. Ways of improving validity by this token include triangulation, respondent validation or member checking, providing a clear account of the processes of data collection and analysis, demonstrating researcher reflexivity and attention to negative cases. In addition, fair dealing which demonstrates that the researcher has included a wide range of different perspectives ensures that no potential viewpoint is neglected.

3.5.4 Validity and reliability in this study

In this study the researcher used the criteria of validity and reliability throughout. The reasons for this were as follows;

- The research design incorporated both qualitative and quantitative elements and therefore it seemed practical to use consistent terminology.
- The debate regarding the use of the criteria remains unresolved and therefore there was no one over-riding argument against this stance. Furthermore, several prominent writers in the field of research (Bryman 2004; Mays and Pope 2000; Murphy et al 1998) proposed the acceptance of the criteria of validity and reliability provided the aims of the research were met.
- The means by which the researcher demonstrated quality were method appropriate in line with Bryman (2004), Mays and Pope (2000) and Murphy et al (1998).

An explanation of the ways in which validity and reliability were applied to this study is found in section 6.5.

3.6 Ethical issues

3.6.1 Ethics in research

Ethics is a branch of philosophy concerned with morality and what is considered to be right or wrong in society (Beauchamp and Childress 1994). Ethics in research became prominent following the abuse of human rights under the guise of research including Nazi experimentation and led to a number of ethical codes being formulated and adopted by those involved in research (British Medical Association (BMA) 2001). The BMA stated the purpose of research in health is to contribute to the existing body of knowledge on a given topic by the use of precise and robust methods.

However the research process may result in the disclosure of information about individuals that is not already known (McHaffie 2000) and therefore the entire research process is subject to a number of ethical considerations from the choosing of the research topic through to the dissemination of the findings (Parahoo 1997). A number of ethical principles exist which form the basis of ethical research namely autonomy, non-maleficence, beneficence and justice (Beauchamp and Childress 1994).

3.6.2 Autonomy

The literal meaning of autonomy is 'self-rule' and was first used to describe the self-governance of the ancient Greek Hellenic city-states (Beauchamp and Childress 1994). The concept of autonomy has been widened to include individuals and has various definitions including "self-governance", "freedom of the will" and "being one's own person" (Beauchamp and Childress 1994, p120). The Royal College of Nursing (RCN) define autonomy as being "the ability of an individual to make reasoned decisions about issues that affect them" (RCN 1994, p4). Thus the autonomous individual has the capacity to act in a self-determining way although as Beauchamp and Childress (1994) point out, capacity to act autonomously is not the same as actually acting autonomously, in other words people can fail to act autonomously.

In order to be autonomous, individuals must possess "liberty" (independence from controlling influences) and "agency" (capacity for intentional action) (Beauchamp and Childress 1994, p121). The BMA (2001, p37) describe the components of autonomy as being "understanding, the absence of mental illness and social opportunity" which compares with Beauchamp and Childress' concepts. Thus it can be seen that whilst respect for autonomy is a guiding ethical principle (Beauchamp and Childress 1994), not all individuals have the capacity or the opportunity to act autonomously.

Research has the potential to threaten a person's autonomy in several ways (BMA 2001);

- The researcher may have power or influence over the research participants
- The research subjects may form part of a vulnerable population and feel obligated to take part in the research
- The eligibility criteria of the study may exclude individuals thus denying their chance to take part in the research.

Polit et al (2001) state that to respect participants' autonomy, participation must be voluntary and participants made aware of their right to decline participation or withdraw from the study at any time without prejudice. The BMA (2001) however caution that simply being invited to take part in a study by a health care professional may give the study credibility and vulnerable patients may agree to participate to 'help' the health care professional which could in turn challenge a person's autonomy. This is echoed by Redsell and Cheater (2001) who state that patients recruited into studies by a nurse known to them may consent in order to please the nurse.

Beauchamp and Childress (1994) state that autonomous decision making and informed consent are inextricably linked in biomedical ethics. The physician is obliged to inform by providing full and comprehensive information to the patient and also to insure that the information given is able to be understood by the patient (Beauchamp and Childress 1994). Consent involves the individual's free choice to proceed in the matter after being informed (Beauchamp and Childress 1994). Thus informed consent requires that the individual receives and understands adequate and appropriate information and voluntarily consents to the care, treatment or intervention. Beauchamp and Childress (1994) further state that the researcher is thus obligated to insure informed consent from potential and actual research participants in order to address the principle of respect for autonomy.

In addition, although individuals may make an autonomous decision to take part in research, there remains the potential for the research to cause harm for example by exposing them to side effects of new drugs or by disclosing intimate personal details in interviews. Therefore it stands that autonomy does not exist in isolation but is a component of an ethical framework inclusive of the other guiding principles.

3.6.3 Non-maleficence and beneficence

Non-maleficence is defined as the moral obligation not to harm whilst beneficence is to do good (Beauchamp and Childress 1994). It is further defined that 'harm' can be both physical and emotional (Bryman 2004).

Some moral philosophers have argued that the obligations of non-maleficence are more rigorous than those of beneficence (Beauchamp and Childress 1994). Thus a person is obligated first and foremost to do no harm but the obligation to do good is more passive. For example, a person is less obligated to jump into a river to save someone from drowning than to act not to throw them into the river in the first instance. Beauchamp and Childress dispute this and claim that although the concepts of non-maleficence and beneficence are distinct, they are both important and should not be ranked in any way hierarchical way.

Non-maleficence and beneficence are important concepts in the research process in part owing to the unpredictable element of discovery embedded in research (Orb, Eisenhauer and Wynaden 2001). The BMA (2001) further explain that the quest to produce research-based knowledge to do good could result in doing harm to individuals. To find a cure for cancer, one may expose research participants to the unwanted side effects of new drugs, a concern even when an autonomous decision to take part has been made.

However, it could be argued that it is impossible to eliminate all potential physical and emotional harm from the research process therefore the most important issue is that the researcher strives to promote non-maleficence and beneficence. Polit et al (2001, p76) summarise this well as the "risk/benefit ratio" in research. They provide a framework which allows the researcher to consider the potential benefits of the research against the potential harm to participants and ensures that the proposed benefits never take precedence over the individual risks to participants.

3.6.4 Justice

The principle of justice refers to an individual's right to be treated fairly and equally (Polit et al 2001; Orb et al 2001). Beauchamp and Childress (1994) further explain that injustice therefore incorporates an act or omission that denies an individual their right to a resource or privilege. To act in a just way also insures that people are not exploited or abused (Orb et al 2001).

In terms of the research process, this means that all individuals who may benefit from the research should have the opportunity to take part and has implications for the setting of eligibility criteria (Polit et al 2001). Non-justifiable exclusion of a particular group of patients from a drug trial for example could mean that future similar patients are denied the drug.

Other ways of acting in a just way in research include being sensitive to participants needs and concerns, acting in a respectful manner towards participants, providing the opportunity to clarify participants' concerns and respecting all arrangements agreed with the participant (Polit et al 2001).

As well as the above underlying principles of ethical research there exist a number of related issues which must be addressed in any research study and which help to insure proper conduct in a study (Bryman 2004; Polit et al 2001; RCN 2001).

3.6.5 Confidentiality and anonymity

Research in humans may encroach into aspects of the individual's personal life therefore participants have the right to privacy (Polit et al 2001). The concepts of confidentiality and anonymity are used to safeguard privacy.

Confidentiality in research means that the identities of participants or the information they provide is not displayed in the public arena without their prior consent (Polit et al 2001). Anonymity refers to the process of insuring that the information provided by participants is unable to be linked back to them in any way thus the researcher is unable to tell who provided which data (Polit et al 2001). For Polit et al (2001) the right to confidentiality is implicit in the principle of justice, meaning that participants are treated fairly and the information they provide is treated with the same respect.

It follows that while all data can be treated confidentially, not all data can be anonymized. Whilst the self-report questionnaire can be anonymized it is not possible to anonymize the data in interviews, observations and experiments. In such circumstances, researchers must treat the data confidentially for example by using identification codes in place of participants' names, to insure that no one other than those consented to by participants is able to link the data with the participant (Polit et al 2001). Furthermore, the data obtained must be edited to insure that the participant is not identifiable from other means such as age, occupation or distinguishing features (Redsell and Cheater 2001).

This has implications for researchers in terms of how data is recorded and stored. The researcher's responsibilities with respect to this are laid out in the 1998 Data Protection Act.

3.6.6 Data Protection Act

The Data Protection Act (UK Parliament 1998) was introduced to insure that information about individuals was treated fairly and lawfully. The Act gives individuals certain rights regarding information held about them and who can access it and covers factual information relating to the

individual and opinions held by them (UK Parliament 1998). There are eight principles of good practice relating to the holding of personal information; the information must be;

- Fairly and lawfully processed
- Processed for limited and specific purposes
- Accurate and up to date
- Adequate, relevant and not excessive in relation to the purpose(s) for which they are processed
- Not kept longer than necessary
- Processed in accordance with the individual's rights
- Securely held to insure no unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data
- Not transferred to countries outside the European Economic area unless country has adequate protection for the individual.

Interestingly personal data obtained for research purposes is exempt from certain aspects of the Act provided particular guidelines are followed (Redsell and Cheater 2001). An example is that personal data obtained from research can be kept indefinitely (UK Parliament 1998). Nonetheless it is stated that personal information obtained through research must be treated confidentially and must not be processed in such a way as to cause damage or distress to the individual concerned (UK Parliament 1998).

The Data Protection Act also makes it a criminal offence to distribute personal information about an individual or to allow access to personal information without prior consent from the individual. The implications of this are discussed by Redsell and Cheater (2001) who found that confusion regarding aspects of the Act exists in the health service and academic community. Redsell and Cheater (2001) cite two instances where they believe bias was introduced into a study as a result of how the Data Protection Act was interpreted. In one study the researcher was not given ethics approval to recruit participants but rather had to recruit through a third party known to the participants; in this instance a nurse; as the ethics committee deemed that to give the researcher potential participants' details would contravene the Data Protection Act. Thus the researcher had no way of knowing which potential participants were approached or whether potential participants were not asked to participate for reasons related to

the recruiting nurse rather than the study (Redsell and Cheater 2001). In the second study, the Data Protection Act was contravened as contact details of staff were provided to researchers without the prior consent of the individuals involved (Redsell and Charter 2001). Redsell and Cheater conclude by stating that the Data Protection Act has implications on study design and execution and that the researcher must insure methodological rigour is not compromised as a result.

3.6.7 Deception

Bryman (2004) states that deception can occur in research in a number of ways including deceiving participants as to the true aims of the study, not providing participants with enough information regarding the study and presenting unsubstantiated findings. Bryman (2004) argues that some degree of deception is widespread in research as it may not be possible or desirable to fully inform every individual participant of every aspect of the research. However, Polit et al (2001) caution that deception can interfere with a person's autonomous decision making and therefore participants must be fully informed of all relevant and necessary information. It could also be argued that deception is potentially problematic in qualitative research when the researcher is an instrument of data collection and is linked to the concept of reflexivity which is discussed in section 3.3.3.

3.6.8 Vulnerable/dependant subjects

The use of vulnerable and/or dependent participants raises the potential for abuse in research (BMA 2001). The BMA state that dependant groups such as people with illnesses are often chosen as research subjects and indeed most health-related research is conducted using people with varying illnesses. It is further recognised that almost all research participants are vulnerable to some extent by virtue of being recruited into the arguably uncertain nature of a research study (BMA 2001). Certain groups of individuals are recognised as being particularly vulnerable including children, the mentally handicapped and unconscious patients whose capacity to act autonomously is challenged (BMA 2001; Polit et al 2001).

However, it is further apparent that patients recruited into health-related research studies can demonstrate more subtle forms of dependency and vulnerability (BMA 2001). Patients being treated by a medical team may feel obliged to take part in studies to help or ingratiate themselves to members of the medical team as discussed in section 3.6.3.

Thus vulnerability and dependency are also linked to the concept of autonomy and it could be argued that a person's liberty, or freedom from controlling influences, is challenged when one is under the ongoing care of a medical team.

3.6.9 Ethical issues raised by this study

In this study, the participants were patients receiving cytotoxic chemotherapy for incurable colon cancer and thus were considered as potentially vulnerable and dependant. At the time of data collection the researcher was a member of staff of the Oncology unit where the study took place although none of the participants were known to her. Nonetheless, it was possible that the potential participants may have felt compelled to consent as they recognised her as a staff member or because they felt grateful for the treatment they were receiving. It was thus crucial that potential participants were aware of their rights to decline participation or withdraw from the study at any time without prejudice. Furthermore in order to respect patient autonomy it was necessary to fully inform participants of the nature of the study, that it was not an essential part of their care and that although future patients may benefit from the study results, they themselves would not benefit directly from the study.

There was no potential for the study to cause physical harm to participants although it was possible that emotionally challenging subject matter might come to light as patients discussed the impact of having a PICC line on their lives and those of their families and friends. The mixed methods approach taken also meant that information obtained from the semi-structured interviews was not anonymous but all information was treated confidentially and in accordance with the Data Protection Act (1998). The measures implemented to adhere to ethical research guidelines are described in section 4.5.

CHAPTER FOUR – MATERIALS AND METHODS

4.1 Study aims

The aim of this study was to examine the views and experiences of patients receiving ambulatory MdG chemotherapy via a PICC line. The objectives of the study were:

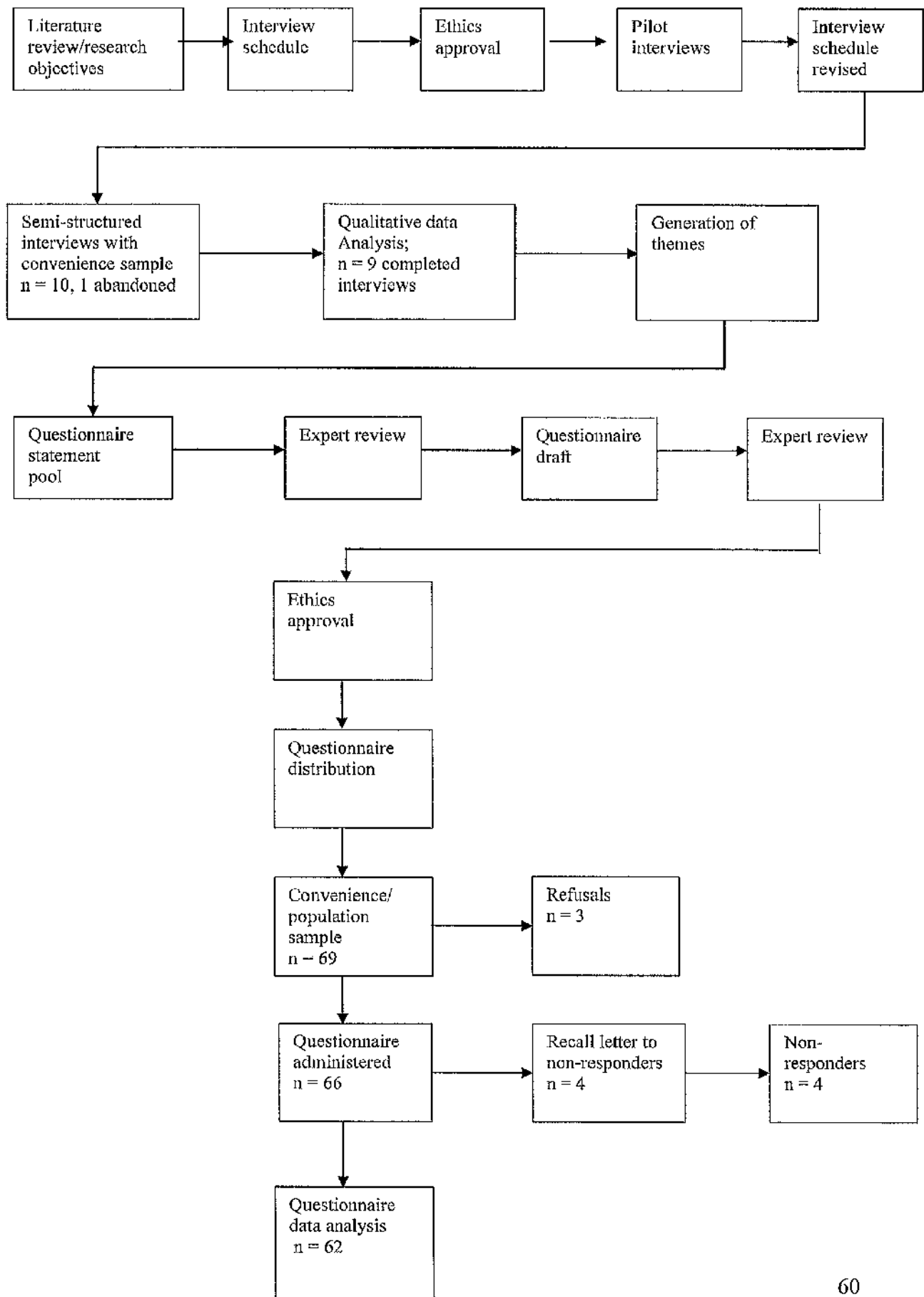
1. To determine which aspects of living with a PICC line cause patients most difficulty.
2. To explore patients' views of the PICC line experience.
3. To determine if patients view PICC lines as a benefit or a burden when receiving ambulatory MdG chemotherapy.

This chapter outlines the steps taken in conducting the study and describes the study design, study sample, ethical considerations, research instruments, data collection procedures and methods of data analysis. Sections 4.2, 4.3, 4.4 and 4.5 are applicable to both phases of the study. Following these sections, the two phases of the study are described sequentially.

4.2 Overview of study design

This was a multi-method triangulated descriptive study implemented in two phases over two years and employing both qualitative and quantitative methods. Phase 1 involved the collection of qualitative data through semi-structured interviews from a convenience sample of 10 participants. The qualitative data were analysed using content analysis from which emerging categories and themes were produced. The themes were used to construct a questionnaire for use in Phase 2 from which quantitative data were collected from a convenience sample of 62 participants. Statistical advice was provided and the quantitative data analysed using Minitab.

Figure 1: Illustration of study design



4.3 Study site

The study took place in the chemotherapy day unit of a large oncology centre in Scotland. The Oncology Centre serves a population of >2.8 million patients from five health board areas, both rural and urban. The Centre is a specialist cancer tertiary centre and treats patients with a wide variety of cancers as in and out-patients. Owing to the wide geographical area served, many patients are required to stay away from home or travel long distances in order to receive treatment. In the region of 8,000 new patients attend the Centre yearly and >6,500 courses of radiotherapy and >15,000 courses of chemotherapy are administered. The chemotherapy day unit on average treats approximately 40 patients per day and approximately 500 PICC lines are inserted in patients each year.

4.4 Access

All oncology consultants (n=7) referring patients to the chemotherapy day unit for MdG chemotherapy with a PICC line were informed of the study in writing (Appendix I), issued with a copy of the research proposal and permission to access their patients was requested. All agreed. Access was also requested and granted from the Clinical Nurse Manager of the Centre, the Chemotherapy Service Senior Nurse and the Chemotherapy Day Unit Manager (Appendix II). Members of the chemotherapy nursing team were informed of the study by holding informal briefing sessions and given the opportunity to ask questions or raise concerns. This was considered important since the researcher would spend a considerable amount of time in the unit and because these nurses would be involved in aspects of participant recruitment (see section 4.8). No major concerns were raised and all queries were addressed.

4.5 Ethical considerations and ethics approval

As discussed in section 3.6.10, the ethical issues raised by this study were the vulnerable/dependent nature of the participants, the participants' autonomy, informed consent, potential harm to participants and issues of confidentiality and anonymity, all of which are interlinked.

4.5.1 Respect for autonomy

Autonomy is defined as "the ability of an individual to make reasoned decisions about issues that affect them" (RCN 2004, p4) and can be threatened when research participants are vulnerable or when the researcher has power or influence over the study participants (BMA 2001).

The participants in this study could be considered vulnerable and dependent as they were receiving chemotherapy for terminal cancer. The BMA (2001) states that simply being asked to

participate in a research study can make patients feel obligated and give the study credibility. It is therefore essential that potential participants receive adequate information to allow them to make an informed decision to participate or not and that they are aware of their rights. In this study, this was achieved by providing a patient information sheet (Appendices III and IV) containing explicit information to protect patient autonomy namely;

- The aims and objectives of the study
- Why their participation was being sought
- That participation was entirely voluntary
- That the participants themselves would not directly benefit from the study
- That the participants could withdraw from the study at any time without prejudicing their care
- That the study findings would be made available to others with an interest in the subject.

4.5.2 Informed consent

Informed consent is linked with autonomy (Beauchamp and Childress 1994) and in addition to the measures outlined above, participants were also given time to consider participation and to have any outstanding questions or queries addressed.

For the Phase 1 interviews, written consent was provided by the participants (Appendix IV) stating that they understood the nature, purpose and possible consequences of taking part in the study and that they were free to withdraw at any time.

In Phase 2, the front page of the questionnaire had statements with tick boxes beside them for participants to indicate that they understood questionnaire completion was for research purposes, that they had read and understood the patient information sheet and that they understood participation was voluntary and they could withdraw at any time without prejudice.

4.5.3 Potential harm to participants

The principles of beneficence and non-maleficence are applied in research to insure the risks of research do not outweigh any potential benefits (Polit et al 2001). There was no potential for physical harm in this study. However although unlikely, it was possible that psychological harm could occur as a result of discussing sensitive issues in the interviews. It was therefore decided that should any participant become emotionally distressed during the interview, the researcher would alert the patient's chemotherapy nurse in order that she could ensure the patient's distress was addressed.

4.5.4 Confidentiality/anonymity

All participants have the right to privacy (Polit et al 2001) and the concepts of confidentiality and anonymity are used to safeguard privacy. To insure confidentiality, the participants' identities or the information they provide must not be displayed publicly without their prior consent. Anonymity refers to the process of separating the data from the provider so that no-one is aware of who provided the data.

The patient information sheet made participants aware that the study findings would be made available to others with an interest in the subject but that all information they provided would be treated confidentially. This was insured by using identification codes on both the interview transcripts and questionnaires so that no-one other than the researcher was able to link the data with the participant. Thus the information provided was not anonymous but adequate steps were taken to insure confidentiality and treat the information in accordance with the Data Protection Act (UK Parliament 1998). The data were stored either on a password protected computer or in a locked cabinet. Participants' details were kept separate from their responses at all times by use of the identification code and the data were enough to answer the research questions but not excessive. The data were held until the study was completed and published then destroyed in accordance with the 1998 Data Protection Act.

4.5.5 Ethics Committee Requirements

For this study, ethics approval was obtained from the Local Research Ethics Committee (LREC). The triangulated study design meant that submission for ethics approval was required on two occasions.

Submission to LREC was made on December 2003 for ethics approval to undertake the Phase 1 interviews and on January 2004 to undertake the Phase 2 questionnaires. On both occasions, minor adjustments were required to the accompanying Patient Information Sheet and on the second submission; the addition of a medical clinician's name to the application was required. Following these minor adjustments formal ethics approval was granted (Appendices VI and VII).

4.6 Phase 1 sample and sample size

A convenience sample was used to collect the qualitative data through the semi-structured interviews. Although recognised as the weakest form of sampling (Polit et al 2001), it is often used by nurse researchers and in qualitative designs (Polit et al 2001; Parahoo 1997). Additionally there was not enough pre-existing information available to determine any potential variables which could have been used to specify the requirements of a purposive or quota

sample which are generally considered to be more robust methods of obtaining a qualitative sample (Polit et al 2001; Oppenheim 1992). In this study, three participants took part in the pilot study and five male and five females took part in the main study interviews. Polit et al (2001) state that smaller samples of 10 or less are usually sufficient for qualitative studies.

4.6.1 Inclusion criteria

- PICC line in situ for at least 8 weeks
- ≥ 18 years of age
- attending day unit at study site
- receiving any MdG chemotherapy regimen
- willing and able to give informed consent

4.6.2 Exclusion criteria

- unable to read or write English

4.6.3 Justification for inclusion/exclusion criteria

The period of eight weeks was chosen as this allowed for a reasonable period of time to assess day to day living and for patients to have experienced living with the PICC line in situ.

It was decided to sample patients receiving MdG chemotherapy in order to target a more homogenous population. As described in section 2.5.4, PICC lines are used for the administration of a wide variety of chemotherapy regimens including short bolus administration, intermittent infusion and continuous pump. By sampling only MdG PICC-line patients, potential sources of bias such as the severity of toxicities which could affect participants' perceptions of daily life were reduced (Meredith and Wood 1996). Furthermore, there are less 'badges' of cancer in this group of patients such as alopecia which could make it difficult to distinguish between PICC-line related altered body image perception and that induced by other causes (Daniels 1996).

In addition to the inclusion/exclusion criteria, World Health Organisation (WHO) Performance Status and toxicity assessment (Appendix VIII) took place prior to participants' interviews. The researcher decided that those with Performance Status > two and those experiencing >Grade two toxicities would have their interview postponed or cancelled for two reasons: it would have been inappropriate to ask an ill patient to sit through a fairly extensive interview. Secondly, if a participant was particularly unwell at the time of interview, this could introduce a potential

source of bias, since it has been recognised that the patients' condition can be a significant variable in assessing responses to particular questions (Meredith and Wood 1996).

4.7 Construction of the Phase 1 semi-structured interview schedule

Justification for the Phase 1 data collection method chosen is provided in section 3.3. The aim of the interviews was to provide qualitative data which could be analysed for themes that would contribute to the development of the Phase 2 questionnaire.

The interview schedule (Appendix IX) was developed taking into account the specific aims of the research and key findings from the literature review. Consideration was given to maximising the strengths and reducing the limitations of interviews. The schedule was designed in such a way as to avoid the use of leading and/or ambiguous questions (Bryman 2004). The questions used were open but focussed to allow the participants to give answers in their own words but also to ensure they remained focussed on the aims of the study (Parahoo 1997). Questions were kept short and the use of jargon avoided (Oppenheim 1992). The number of questions used was considered carefully to avoid overburdening participants and to ensure the interviews were not too lengthy or tiring (Bryman 2004). The final question allowed participants the opportunity to add anything they thought relevant that was not already covered (Oppenheim 1992).

The devised interview schedule was subject to piloting following which several minor adjustments were required (see 4.9.4).

4.8 Phase 1 Recruitment strategy

The steps taken in recruiting participants for the Phase 1 interviews were as follows:

1. A checklist detailing the study inclusion/exclusion criteria was drawn up.
2. Potential participants were identified from the chemotherapy day unit admissions list by a member of the chemotherapy nursing team.
3. The chemotherapy nurse checked eligibility using the patient's case notes and the checklist described above.
4. Potential participants were issued with a patient information sheet (Appendix III) by the chemotherapy nurse and willingness to participate confirmed.
5. The potential participant was identified to the researcher by the chemotherapy nurse.
6. The researcher approached the potential participant, checked eligibility criteria, answered any outstanding questions and obtained written consent.

4.9 Phase 1 pilot study

Pilot studies allow for testing of the researcher as a tool for data collection (Mason 1992); testing of the data collection methods (Clifford 1997) and also afford the researcher the opportunity to develop and practise their interviewing skills (Holloway and Wheeler 2002; Mason 1992).

4.9.1 Pilot study objectives

1. To assess the suitability of the room environment for interviews.
2. To test the quality of recording equipment.
3. To assess the suitability of the recruitment strategy.
4. To allow the testing of interview questions in terms of participants' understanding and sequence of questions.
5. To commence the process of reflexivity, especially in relation to the researcher's interview style.
6. To familiarise the researcher with the process of data analysis
7. To examine the quality of the data generated in terms of meeting the aims of the study.

4.9.2 Pilot study data collection

The pilot interviews were carried out in the room intended for use in the main study. The proposed interview schedule was used. A convenience sample of two participants who met the eligibility criteria was involved in the pilot interviews. The steps outlined in section 4.8 above were carried out following which the researcher and participant agreed a mutually convenient date and time for interview. On the day of interview the participant was given the opportunity to discuss any outstanding questions or queries. The researcher then assessed the WHO performance status and toxicity assessment prior to conducting the interview. These were satisfactory and the interviews proceeded. The interviews were audio-taped and then transcribed verbatim. Field notes were written up immediately following the interviews and included a personal assessment of the researcher's interview performance.

4.9.3 Pilot study findings

The main findings of the pilot study with regard to the objectives were as follows;

1. The room was satisfactory for interviews.
2. The recording equipment adequately recorded both researcher and participants' words and there were no problems with the transcribing of tapes.
3. The process of recruiting participants worked well and no problems were identified.
4. Two of the original interview questions needed to be altered as it was clear that both participants had difficulty understanding what information was being requested. One

question was reviewed and effectively became two separate questions and a further question was rephrased. The sequencing of the questions appeared satisfactory.

5. The interviews appeared to flow well overall. The researcher had previously undergone training in communication and counselling skills, many of which were transferable to this type of interview situation; for example, active listening skills, non-verbal communication cues and remaining silent when necessary. However, there was a degree of anxiety present, which may have been apparent as one participant commented that "you look very serious" and the researcher felt that her performance as an interviewer could be improved upon. It was also evident that the two initial pilot interviews were very unequal in terms of length with interview one lasting seven minutes and interview two lasting 25 minutes. It was not clear whether this variation was a result of interview technique or participant behaviour, but the short length of the first interview was seen as being a concern as further short interviews could potentially impact on the amount of useful data gathered.
6. The researcher was able to familiarise herself with the data analysis process.
7. The data generated from the pilot interviews appeared consistent with the aims of the research.

The pilot study also yielded further valuable in relation to the use of field notes.

The field notes made after the pilot interviews consisted almost entirely of information relating to the researcher's performance. Whilst this was an important objective of the pilot study, the lack of observation in relation to other aspects of the interviews was seen as lacking. It was therefore decided to construct a template to be used during further interviews as a means of structuring the field notes and making them more systematic and robust. The template (Appendix X) would serve to prompt the researcher to write down notes relating to other important interview features such as participants' non-verbal communications, any surprising findings/feelings or any other factors the researcher felt might be affecting the interview.

Taking all of the above into account, it was decided to carry out a further pilot interview to allow the researcher further practice of technique, better estimation of interview time and to further test interview questions in light of alterations made. The third pilot interview was carried out in accordance with all existing criteria governing the initial two pilot interviews. Following the third pilot, it was felt that the extra practice obtained had been valuable and the researcher felt confident to move on to the main study with no further alterations necessary.

Patients participating in the pilot interviews were excluded from the main study.

4.10 Phase 1 Main study

4.10.1 Recruitment

Data collection for the semi-structured interviews took place between March and May 2004. Potential participants were identified from the chemotherapy day unit admissions list by a member of the chemotherapy nursing team, eligibility criteria checked and then provided with a patient information sheet to read and consider. The chemotherapy nurse then obtained verbal consent and alerted the researcher of a potential participant. The researcher then approached the patient, confirmed their willingness to participate, checked study eligibility and answered any outstanding questions. A mutually convenient date and time for interview was then arranged. All participants elected to have the interview carried out during their next scheduled chemotherapy appointment. In total, 11 patients (six male) were approached to take part in the Phase 1 of the study. One male patient declined (no reason was sought) and one male patient was unable to complete the interview. None of the participants were known to the researcher.

4.10.2 Semi-structured interviews process

All interviews took place in a quiet, non-clinical room adjacent to the chemotherapy unit and were carried out by the researcher. Immediately prior to each interview, the researcher carried out a final assessment of WHO Performance Status and toxicity grading to ensure each participant was fit enough to be interviewed. Both were satisfactory in all participants allowing all interviews to proceed. The interview schedule was adhered to and the researcher paid particular attention to applying the skills of good interviewing. Care was taken to ensure adequate understanding of the questions and time was allowed for the participant to respond. The researcher maintained a neutral posture during the interviews and was mindful of body language and other non-verbal communications. Gentle encouragement was given when needed.

The interviews varied in length from eight minutes to 32 minutes, averaging 19 minutes. As with the pilot study, any initial anxiety on the part of the researcher quickly faded and there was no difficulty in establishing rapport with the participants. Generally, the participants answered the questions without hesitancy.

The interviews progressed without any difficulties with one exception. During this interview, the participant began to complain of feeling nauseous approximately half way into the interview. The participant at this time stated his willingness to continue. However the researcher decided to end the interview as it appeared that the participant's main concern was in "letting down" the researcher. Assurance was given that this was not the case and the

participant was returned to the unit and his care taken over by the chemotherapy nurse. This participant's responses were omitted from the data analysis for reasons previously outlined in section 4.5.3 and also because the data collected were only partially complete. Furthermore, it was decided that it would be inappropriate to re-schedule the interview on the grounds that the participant may have felt obligated to take part.

The interviews were tape-recorded with participant permission and the researcher completed field notes immediately following the interview to avoid disturbing the participant or obstructing the flow (Holloway and Wheeler 2002; Polit, Beck and Hungler 2001). The researcher used a template to order the field notes and to serve as an aide-memoire when detailing any factors which may have influenced the interviews as described in section 4.9.4.

The recorded interviews were transcribed verbatim by the researcher and analysed using Microsoft Word. It was decided not to carry out a replacement interview for the incomplete interview as the data obtained was already voluminous and because of the time constraints of the study.

4.10.3 Phase 1 data analysis

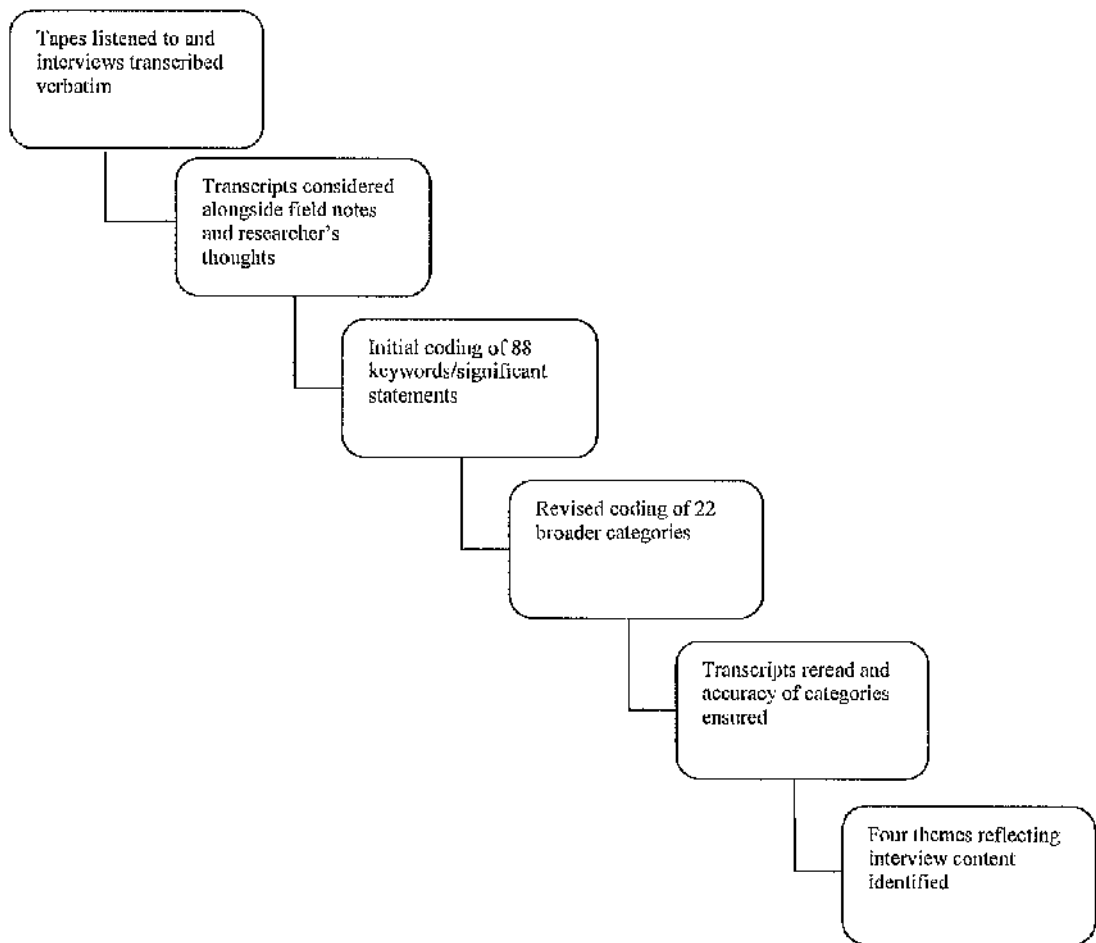
Data analysis took place after all interviews had been completed to ensure that the initial findings did not influence ongoing interviews. Manifest content analysis was appropriate for the analysis of the qualitative data and justification for this is provided in Chapter three. In keeping with the aims of manifest content (see 3.3.4), the researcher focussed on drawing out the data which addressed the study aims. This involved studying the texts, analysing the words and grouping them into a smaller number of content related categories (Cavanagh 1997).

The following description details the application of manifest content analysis to the qualitative data.

1. Immersion in the data was obtained by listening to the audio-tapes and manually transcribing verbatim.
2. The field notes were read with the transcripts and notes made on the transcripts reflecting the researcher's thoughts regarding the emerging themes. For example, one participant had stated that he "couldn't wait to get the thing (PICC line) out" but was on his last treatment and was referring to the relief of finishing chemotherapy rather than implying that he had negative views towards the PICC line. Thus it was important to regard the patients' words in the context within which they were intended, with the field notes providing additional evidence.

3. The transcripts were then read again and keywords/significant statements highlighted on the transcripts. This was carried out line by line and often reflected the participants' actual words; for example, "it could be worse". This initial coding generated 88 keywords/significant statements (Appendix XI).
4. The keywords/significant statements were considered and compared and reorganized into a smaller number of broader categories (Appendix XII).
5. The transcripts were read again to ensure the categories were a true reflection of the interview content.
6. The categories were considered further and the underlying themes identified. This resulted in a final list of four themes (Appendix XIII) which the researcher believed accurately described the thematic content of the interviews: impact on daily life, information giving, responsibility/coping at home and adaptation/acceptance.

Figure 2: thematic analysis steps



4.11 Phase 2 sample and sample size

It was decided to include all patients who met the eligibility criteria during the timeframe of Phase 2 data collection. The researcher was able to determine the approximate number of potential participants from activity data of the unit where data collection was being carried out and ascertained the number of potential participants would be manageable. Therefore by including all eligible patients as potential participants, the sample would be representative of the target population providing there were minimal non-responders.

Consecutive eligible participants who presented and met study criteria between January 2005 and June 2005 were approached to take part in Phase 2 of the study (n=69). There were three outright refusals and four non-responders therefore the final sample size was 62.

4.11.1 Inclusion criteria

Inclusion criteria for Phase 2 of the study were the same as those used in Phase 1 (see 4.5.1).

4.11.2 Exclusion criteria

The exclusion criteria for Phase 2 of the study were the same as those used in Phase 1 (see 4.5.2). In addition, those who participated in Phase 1 were excluded from Phase 2. As discussed in section 4.5, the patients recruited in this study had a terminal illness and therefore to ask for participation in both phases of the study was seen as being excessive.

4.12 Construction of phase 2 questionnaire

The themes generated from the Phase 1 interviews were used to construct a questionnaire for use in Phase 2 to address the aims and objectives of the study. Justification for this approach is provided in Chapter 3.

4.12.1 General considerations

The questionnaire was constructed to minimise bias and ensure the study aims were met. Furthermore, consideration was given to methods of increasing response rates which also increases study robustness (Oppenheim 1992). These include the use of clear instructions, a simple layout, consistent headings, easy to read type face, short sentences, and the avoidance of jargon (Bryman 2004). A time limit for return of the questionnaire was stated (Bryman 2004; Oppenheim 1992) as two weeks. Personal and demographic questions were placed at the beginning to ease participants into the questionnaire (Oppenheim 1992). To maximise data collection, the questionnaires were coded to allow a recall letter (Appendix XV) to be issued to non-responders. As discussed in section 4.5, this information was available only to the researcher and was used to only to issue recall letters. The questionnaire included a column

clearly marked "for office use only" for coding purposes. A final section was also included allowing participants the opportunity to add anything of relevance not covered elsewhere, again contributing to the validity of the findings (Oppenheim 1992).

4.12.2 Construction of Likert-type scale

Four themes relating to the PICC line experience were generated from the Phase 1 interviews: impact on daily life, information giving, responsibility/coping at home and adaptation/acceptance. Each theme became the basis for a section of the questionnaire.

Impact on daily life

The aim of this section of the questionnaire was to determine which aspects of living with a PICC line caused patients most difficulty. The daily life activities for inclusion in the questionnaire were taken from the Phase 1 interview responses and the key literature review findings. A list of 13 daily life activities was drawn up and space was also provided for participants to add any other daily life activity affected by the PICC line but not covered in the list.

The possible responses were "about the same", "a little more difficult", "a lot more difficult" and "can't do because of the PICC line". A "not applicable" response was also provided to allow participants to indicate any activities that they did not carry out before the PICC line was inserted, for example, looking after children and driving.

Information giving

The aim of this section was to explore patients' views regarding the information given to them during their PICC line experience. A pool of 15 statements (Appendix XVI) reflecting both positive and negative opinions regarding information giving in relation to the PICC line experience was generated in keeping with Oppenheim (1992). The statements were developed by considering the Phase 1 interview responses and the key literature review findings in relation to information giving.

Responsibility/coping at home

The aim of this section was to explore patients' views regarding taking responsibility for their PICC line and coping at home with a PICC line. A pool of 17 statements (Appendix XVI) reflecting both positive and negative opinions regarding responsibility and coping at home with the PICC line was generated in keeping with Oppenheim (1992). The statements were developed by considering the Phase 1 interview responses and the key literature review findings in relation to how patients cope at home with a PICC line or other CVAD.

Adaptation/acceptance

The aim of this section was to explore patients' views regarding adapting to the experience of having a PICC line and also to determine if patients perceived a PICC line to be a benefit or a burden. A pool of 15 statements (Appendix XVI) reflecting both positive and negative opinions regarding adapting to having a PICC line was generated in keeping with Oppenheim (1992). The statements were developed by considering the Phase 1 interview responses and the key literature review findings in relation to patients' acceptance of a PICC line or other CVAD.

The process of creating the Likert-type statements generated an item pool of 47 statements for consideration in the questionnaire. An expert panel consisting of a Chemotherapy Clinical Nurse Specialist, an Oncology Research Nurse, a Cancer Nurse Consultant, a Colorectal Clinical Nurse Specialist and an Oncology Practice Development Nurse were provided with the item pool, the 88 keywords/significant statements from the initial coding of the Phase 1 interview transcripts (Appendix XI) and the final resulting themes from the Phase 1 interviews (Appendix XII). The panel was asked to identify items from the pool for inclusion in the questionnaire on the basis of ease of understanding and representativeness of the interview themes.

The experts' responses were considered and the pool items accepted or rejected on the strength of the level of agreement between the experts. Those with the greatest inter-rater agreement were accepted and those with low inter-rater agreement rejected. Statements which the experts were uncertain of were reviewed further by the researcher and compared with the literature review findings and interview transcripts to determine which statements belonged in the questionnaire. The researcher then decided which statements 'sat' best in the questionnaire to ensure an approximately equal number of both positive and negative statements (Oppenheim 1992), and to reflect overall the themes from the interviews. This left the researcher with 35 items covering the 'information giving', 'responsibility/coping at home' and 'adaptation/acceptance' sections of the questionnaire.

This study employed a 5-point Likert-type scale with the possible responses of 'agree', 'strongly agree', 'neither agree nor disagree', 'disagree' and 'strongly disagree' as it is the most commonly used Likert scale and has been shown to aid data analysis (Jamieson 2004; Edelman 2000; Oppenheim 1992). A neutral position was valid and acceptable as it may have been that some participants were ambivalent regarding certain aspects of the PICC line experience (Priest et al 1995; Oppenheim 1992).

The draft questionnaire was then circulated to the expert panel to comment on general layout, ease of understanding, sequencing of sections, ease of completion and content validity. This led to the following minor amendments;

- Question 3: the possible responses were 'less than 10 miles', 'between 10 and 20 miles', 'between 20 and 30 miles' and 'more than 30 miles'. The third possible response was changed to 'between 21 and 30 miles' to prevent overlap.
- Question 6: the words 'for this course of chemotherapy' were added to the sentence 'How many PICC lines have you had in?' to ensure respondents knew exactly what information was being requested.
- Question 7: the words 'for this course of chemotherapy only' were added to the sentence 'When was your PICC line first put in?' to ensure respondents were referring only to the current chemotherapy treatment with a PICC line.

Following the changes, the final questionnaire (Appendix XIV) was returned to the expert panel who agreed no more changes were required. The time constraints of the study meant that the questionnaire was not piloted with patients since it had been tested by the expert panel and it was unlikely that further testing would add any additional value.

4.13 Phase 2 Recruitment Strategy

The steps taken in recruiting participants for the Phase 2 questionnaires were as follows;

1. A checklist detailing the inclusion/exclusion criteria for Phase 2 of the study was drawn up.
2. Potential participants were identified from the chemotherapy day unit admissions list by a member of the chemotherapy nursing team.
3. The potential participant was identified to the researcher by the chemotherapy nurse.
4. The researcher checked eligibility using the patient's case notes and the checklist described above.
5. The researcher approached the potential participant, provided a patient information sheet (Appendix IV) and outlined the intent of the study.
6. The researcher returned to the potential participant once the patient information sheet had been read and those who agreed to take part were given the questionnaire and reply-paid envelope.

4.14 Phase 2 Main Study

4.14.1 Process

Data collection for the questionnaires took place between January and June 2005. The researcher used the chemotherapy appointments list to determine when potential participants would be attending the unit.

The steps outlined above in section 4.13 were adhered to. The researcher approached all potential participants and outlined briefly the nature and intent of the study. Potential participants were informed that any participation was voluntary and their care would not be affected in any way should they decline to participate. The majority of potential participants appeared interested in the study and many commented on its patient-focussed orientation. Some participants signalled their willingness to participate prior to reading the patient information sheet however all potential participants were given time alone to read and consider. The researcher then returned to the potential participant and addressed any outstanding queries. Those who gave verbal agreement to participation were given the questionnaire and the researcher demonstrated how it should be completed. A reply-paid envelope was provided and it was requested that the questionnaire be returned to the researcher within two weeks.

The majority of participants elected to complete the questionnaire whilst in the day unit, stating that it would help pass the time during chemotherapy administration. However 12 participants did not complete the questionnaire whilst in attendance at the unit. Of these 12, eight were returned within the two weeks. Four were not returned within the two weeks and a recall was issued. Despite the recall, these four questionnaires were still not returned and no further action was taken.

A further three potential participants declined participation in the study. One participant declined stating that he "could not be bothered". The remaining two participants offered no explanation and none were sought by the researcher.

None of the participants were known to the researcher.

4.14.2 Phase 2 data analysis

The Phase 2 data were analysed using both descriptive and inferential statistics and all statistical analysis was carried out in conjunction with advice from a statistician.

It will be recalled that the questionnaire used in Phase 2 of this study had five sections. These were demographic data plus 'impact on daily life', 'responsibility/coping at home', 'information giving', and 'adaptation/acceptance'.

The initial frequency data were summarised using basic descriptive statistics to describe the characteristics of the sample (see 3.4.4). This showed the commonly held views of respondents towards different aspects of the PICC-line experience. More detailed analysis of the data was then carried out to explore the areas where there was less consensus among respondents. Inferential statistics were used to determine which views were most likely to be held by the population represented by the sample in this study.

The Likert-type scale collected data which constituted a single sample ordinal data that was analysed using Confidence Interval (CI) estimation (see 3.4.4). The aim of analysis was to describe the patients' views regarding aspects of the PICC line experience in terms of the population proportions for each of the variables (questionnaire statement responses).

On statistical advice the agree/strongly agree and the disagree/strongly disagree responses were treated as paired samples and the differences between the CIs were calculated. This was to determine if there was a significant difference in the population proportions who agree/strongly agree or disagreed/strongly disagreed with each statement. The interval estimates of the difference in population proportions showed the following;

- questionnaire statements for which there was no significant difference between those who agreed and those who disagree with the statement
- questionnaire statements for which a significantly larger population proportion agreed than disagreed with the statement
- questionnaire statements for which a significantly larger population proportion disagreed than agreed with the statement.

This meant that it was possible to determine the views which were representative of the MdG population towards aspects of the PICC-line experience and also to determine the views for which there was less consensus.

The 'impact on daily life' section of the questionnaire also collected data which constituted a single sample ordinal data that was subject to analysis using Confidence Interval (CI) estimation. The aim of analysis was to describe patients' views regarding which aspects of daily life were most affected by the PICC line terms of the population proportions for each of

the variables (daily life activities). To aid analysis and on the advice of a statistician, interval estimates for the population proportion reporting that the level of difficulty was "about the same" or "a little more difficult" were grouped together as it was assumed that the resulting impact on daily life would be comparable. This allowed each variable to be considered independently in terms of how likely it was to be representative of the views of the population in this study and identified the daily life activities most disrupted by PICC-line insertion.

Space was provided at the end of the questionnaire for respondents to add any additional comments about their PICC line experience. These comments were listed and the thematic content noted.

CHAPTER FIVE – STUDY FINDINGS

5.1 Phase 1 findings

This two-phase study used data obtained from interviews in Phase 1 to develop a questionnaire for use in Phase 2. This section presents the findings from Phase 1. Manifest content analysis was used to analyse the qualitative data (see section 4.10.3) and the themes developed from the interview transcripts are listed in Table 1 below.

Table 1: Phase 1 interview themes

Theme	Initial coding of interview data
Impact on daily life	Need to buy new clothes/alter clothes. Unable to engage in hobbies. Difficulty washing, sleeping, dressing, housework, washing hair, showering, bathing, driving, working, looking after children. Feel unclean. Life not normal. Holidays affected.
Information giving	Did not know what a PICC line was. More practical advice needed. Too much information. Unprepared for insertion. Insertion unpleasant/okay. Some information scary. Doctors/nurses need to tell patient everything. Too much negative/technical information. Unsure what to expect.
Responsibility/coping at home	Staying out of hospital a bonus. Fear being away from expert help. Other health care professionals unsure. Family affected/not affected. Fear of chemotherapy spill, PICC line fault/damage, line being pulled, being in crowds. Too much responsibility on patient/family. Not relaxed at home. Well supported by staff at the unit.
Adaptation/acceptance	You get used to it. It could be worse. Just get on with it. PICC line becomes a part of you. Need more help at the beginning. PICC line always on your mind. Don't mind/do mind others seeing. Good things more than bad. PICC line made treatment easier to get. No cannulations. Gets easier with time. Would recommend to other patients.

The interview respondents were allocated a letter code to ensure confidentiality.

5.1.1 Response rate

A total of 11 patients who met eligibility criteria (see 4.6) were approached to take part in Phase 1 of the study. One patient declined and one was unable to complete the interview (see 4.10.2). Thus nine participants (82% response rate) completed the semi-structured interviews. More than half ($n=7$) stated they were happy to carry out the interview as it would "help others" and because it would give them something to do whilst waiting for their chemotherapy to begin. Five of the participants were female.

5.1.2 Demographic data

The participants' ages ranged from 42 to 76 years of age. The mean length of time the participants had a PICC line in situ was 13 weeks (Range: 9 – 23 weeks). For the majority of participants (n=7), this was their first experience of having a PICC line. The mean distance travelled by participants to receive treatment was 19 miles (Range: two – 66 miles). No other demographic data were obtained.

5.1.3 Existing PICC line knowledge

At the start of each interview, participants were asked if they had known what a PICC line was prior to requiring one and how they felt about having a PICC line inserted. Most participants had no understanding of what a PICC line was and there was unease and uncertainty about the need for a PICC line. The two participants who knew what a PICC line was, were a nurse who had previously seen PICC lines used in sick children and a patient who had seen PICC lines in other patients during a previous course of chemotherapy.

All participants voiced apprehension at requiring a PICC line with a few further stating that they had felt "scared". There was a perception that a PICC line meant that their chemotherapy treatment was going to be more severe or that their cancer was worse than expected. As one participant said *"I was very shocked in the beginning, once it was explained to me what it (PICC line) was.....it seemed very serious...they tell you that the line will be going straight into your heart and I was really, well not scared as such but it did seem like a big deal and I thought, my god, this is serious"*. Participant (P) 1

Another reported *"I didn't know if it meant the chemo(therapy) was worse or the tumour was worse...maybe I was thinking it was more serious this time and that's why I needed this thing (PICC line) because it was more serious this time, quite scary"*. P2

5.1.4 Theme 1: Impact on daily life

Participants were asked to consider how the PICC line had affected their day to day lives. Seven stated that they found dressing more difficult as a result of the PICC line being in situ. Several had purchased new, looser clothes to accommodate the PICC line whilst others had adapted existing garments. Some of the difficulties with dressing were only apparent when the PICC line was attached to the chemotherapy pump; for example one participant who only wore dresses found it necessary to purchase skirts and tops since the tubing for the pump had to be threaded out from the body at waist level which was not possible when wearing a dress.

In addition to dressing, the PICC line affected other aspects of daily life such as sleeping and washing. Four participants stated that they had difficulty sleeping with a PICC line including P8 who said *"in the beginning, I hardly slept a wink....I've got used to sleeping but it's still not perfect...it's subconscious...in your mind that you can't move around the same"*. Another participant reported an almost complete lack of sleep since the PICC line had been placed. This was attributed both to the fear of a cancer relapse and associated treatment and to the presence of the PICC line.

The majority also reported difficulties with washing, especially bathing and showering owing to a fear of soaking the PICC line dressing or contaminating the PICC line with bathwater. This left some with a feeling of being unclean as they felt unable to have a "proper" wash such as P2 who reported *"having a bath, that was the worst bit....you've got to hang your arm over the side and you can't get a good wash with just one hand"*. Interestingly while three participants stated that nursing staff had informed them it was 'alright' if the PICC line got a little wet as opposed to completely saturated, nonetheless they still wanted to keep the PICC line completely dry for reasons they were not able to explain fully. Another who suffered from very dry skin was unable to use emollients in the bath or adequately apply cream afterwards and as a result complained of dry, itchy skin. Several commented that hair washing was particularly difficult since in effect it required use of both arms or help from a family member.

Four participants stated that they were unable to continue with hobbies or leisure activities as a result of the PICC line; for example golf, swimming, gardening and hill walking. It was reported by one that hill walking meant being too far from medical help if a problem with the PICC line arose. Of the six participants who were able to drive prior to PICC line insertion, all but one continued to drive although this participant's perception was that this was because of a general lack of confidence rather than any physical impairment.

Other reported changes in daily life included not wanting to have children too close in case of contamination or in case a child pulled/damaged the PICC line, general difficulties with housework, cooking and shopping and changes to holiday plans.

5.1.5 Theme 2: Information giving in relation to the PICC line

Participants were asked to comment generally on the experience of having a PICC line. In response a number of negative comments were made surrounding the information given in relation to a PICC line. For example, eight reported that there was too much information or that the information was overwhelming. Six stated further that the information was too technical or frightening and queried the need to be given such detail. There appeared to be acceptance of the

need for health care professionals to give all necessary information but still the participants were often put off by it. As one said, *"I know the doctors and nurses need to tell you all the things that can go wrong so that they can say, you know that you knew what you should be doing or in case you don't want to go ahead with it or thatbut maybe it's just me, but I think nowadays they just tell you too much...I don't want to know about all the bad things, about everything that might go wrong...it's too negative"*. P3

Six thought health care professionals gave patients too much information because of a need to tell patients everything in today's health care climate or as one respondent put it *"Nowadays they (health care professionals) tell you everything just because they have to - so that nobody can come back and sue them for not telling them everything"*. P4

Comments were also made regarding the insertion procedure. Two felt unprepared for insertion and found it unpleasant and uncomfortable although relatively painless. Two others found insertion painless and more straightforward than they had imagined because they felt the information given prior to insertion was quite frightening and perhaps too detailed; *"I'm glad they didn't send the information out to the house because when they explained the procedure to me - that they'd put 50 cm of cabling up the inside of my arm and across my shoulder - I thought 'you can't do that without an anaesthetic' and basically they just said to methey put the cream on the inside of both my elbows and said to go and sit there for half an hour until it takes effect and read this leaflet - I'm glad I was basically trapped by that point because it looked so alarming....so I think it's a good idea that you don't know beforehand or else you might not come in for it"*. P6

Most participants felt that the shock of being informed of the recurrence of their cancer and need for more treatment added to the overall shock of being informed that a PICC line was needed. Generally this was a very anxious time for them and they struggled to take in and make sense of all that was happening around them: *"They gave me a very detailed explanation - I know they need to do that so that everyone gets the same information but even though I knew what it was I was still very frightened. I surprised myself at that because I thought I was pretty much in control until then - maybe it was just hitting home - all that was happening - I've spoken to other patients and they nearly all say the same, you know that they found it scary"*. P9

Seven participants also stated they had a need for specific information such as practical advice about dressing and washing that had not been given or not taken in owing to the volume information given at the same time. In addition, three of this seven said they did not want to

know about the technical aspects of the PICC line or when the PICC line dressing was to be changed or blood samples taken. There was a perception that the management of the PICC lines should be the sole remit of the health care professionals and should not be put on to the patient. As P4 said; *"I don't need to know about...is it flushing you call it?...flushing the line.....and blood tests and stuff....you're the professionals, you take care of that.....just tell me what I can and can't do and that's all I need to know"*.

5.1.6 Theme 3: Responsibility/coping at home

The majority of participants stated that they were grateful to be receiving their chemotherapy at home although one reported initial disappointment that hospital admission was not required. This participant had enjoyed support from other patients during previous hospital admissions but now felt that ambulatory chemotherapy was preferable to being in hospital.

However, despite the positive comments, a number of concerns regarding coping with a PICC line at home were raised.

All participants feared either damaging the PICC line or pulling it out although this fear reduced over time. Other common fears were of the chemotherapy spilling (n=5), fear of general PICC line complications (n=4) and fear of being in crowded places (n=3). Furthermore, although participants were happy they did not require hospital admission to receive chemotherapy, six feared being away from the hospital and professional help and some (n=3) had experienced problems when non-specialist staff were required to deal with the PICC line. This was particularly evident in participants who lived some distance from the specialist centre. District Nurses for example on some occasions had never cared for a PICC line before and resorted to asking the participant questions about care. There had also been times when staff in general hospitals were unsure as to what to do. *"I got admitted back into (name of local hospital) one night and they didn't have a clue about it (the PICC line). It was like an alien had landed on the ward that night and they had to send out to somewhere else to get a nurse that knew what she was doing....I thought that can't be right – pretty bad you know and maybe I should have just come back here (specialist centre).....I could have come to all sorts of trouble and there they are asking me... "when was it last flushed?" and if it had moved and stuff...I didn't know and just gave them the book (PICC line diary) but they said it wasn't filled in right and I felt as if they were saying it was my fault but they were the hopeless ones". P8*

A number of the negative comments raised related to the amount of involvement participants and their informal carers/family members were expected to have in PICC line care.

Two participants voiced strong concerns over their partners' expected role in helping with the PICC line at home. Both stated that it was inappropriate that their wives had been expected to deal with PICC-line problems. This was summed up well by P4 who said *"Things that the nurse also said about responsibilities for your partner ...I wasn't too happy about them asking her to get involved if there's problems with the line and I said 'well wait a wee minute here, I am not putting that sort of responsibility on to my wife'. How in the middle of the night is she going to know if there's a problem? I'm not having that responsibility at all on my family – is it going to turn into septicaemia or phlebitis or thrombosis because that's the actual words they used....frightening names and I said I didn't want my wife having anything to do with that at all"*.

Participants' views were mixed regarding how their friends/families felt about the PICC line. A few believed their families held negative views towards the PICC line while others felt that their families had reacted positively and were keen to find out more. Generally participants tended to go along with what they perceived their families'/friends' feelings to be: the PICC line was kept hidden and not discussed with those less accepting whereas participants reported open discussion with family members and friends who wished to do so.

5.1.7 Theme 4: Adaptation/acceptance

Participants were asked to comment on their overall PICC line experiences and anything they thought it would be useful for other PICC-line patients to know. Most of the comments centred on ways of coping with daily life as a result of changes to sleeping, dressing and so forth. Participants also thought it important that other patients knew living with a PICC line got easier as time went on and any initial difficulties were usually resolved as reported by P2: *"Everything was difficult to begin with ... washing, dressing, sleeping....I mean they tell you it's ok to do this and not to do that but it takes time.....you get used to it (PICC line) eventually, you just need to but to begin with it was like....put your arm in here and there and everything was a bit of a mess but I've got used to it now...I mean I still look forward to getting it out but it's not too bad now"*.

Despite general agreement that participants adapted to having a PICC line, all expressed positive and negative views about the general experience. On the positive side, the main perceived advantages of having a PICC line were: home chemotherapy gave participants a feeling of control over their life, greater independence and reduced the need for venous cannulation to receive chemotherapy. There was a general consensus that the PICC line was a good thing as it meant chemotherapy treatment was being given and two participants further perceived that the chemotherapy would be more effective if given this way because, *"This thing*

(PICC line) means the chemo(therapy) is going straight into my system...this is the quickest way of getting it (chemotherapy) so it will get to the tumour quicker". P7

Although some participants experienced difficulty when non-specialist staff were dealing with the PICC line (see section 5.6), most participants felt well supported by their District Nurse/GP and commented that the PICC line gave them freedom. This was especially important for some who perceived that their life span was now limited such as P10 who said, *"I know I'm dying...I hope I'll get years but the doctors say it's more likely months.....but this line (PICC line) has meant that I've not needed to be away from the house overnight, you know, leaving my own bed, and that's been great.....when you're in hospital everything works round that but if you're at home, it's more like normal for the family".*

However a number of negative comments were also made regarding adapting to having a PICC line in situ. Four participants reported feeling self-conscious as the PICC line signalled to outside observers that something was amiss. This was perceived to be more of a problem when the chemotherapy pump was attached to the PICC line as explained by P4: *"If I've got the pump fitted then I'm very conscious of it – it's a lump sitting there...and when you've got cancer and somebody happens to see you from a distance and says "oh I saw X (patient's name) there and he's got an awful big lump, do you think that's anything to do with his cancer" ...so I'm not going to get a placard saying "by the way I've got a PICC line in and this lump you see is a pump" but it's just during the course of it you're self conscious".*

5.2 Key messages from Phase 1

The interviews revealed that participants held both positive and negative views towards aspects of the PICC line experience. The main advantages reported were not requiring hospital admission, the reduced need for venepuncture and cannulation and the ease of chemotherapy administration. Nonetheless life changed when having ambulatory chemotherapy with a PICC line and daily activities such as washing, dressing, sleeping and engaging in hobbies were affected to various extent. Most participants adapted well to the experience however a number of concerns were evident. These related in the main to the chemotherapy spilling, the PICC line malfunctioning and the PICC line alerting outsiders to the participant's predicament. Furthermore, participants expressed unease over their and their partner's expected level of involvement in PICC-line care.

Information giving to ambulatory chemotherapy patients with a PICC line appeared to be the area of greatest challenge. The interviews showed that although participants felt well supported by staff, they struggled with the volume and nature of the information given to them. The

information was described as **unhelpful**, excessive and at times, frightening. Despite this, the advantages of having a PICC line outweighed the disadvantages for most participants and the general consensus was of adaptation and acceptance.

The Phase 1 themes guided development of the questionnaire (see 4.12) used in Phase 2, the results of which follow.

5.3 Phase 2 results

5.3.1 Introduction

As previously noted, the semi-structured interviews carried out in Phase 1 of the study generated themes and categories which aided development of a questionnaire used in Phase 2.

The Phase 2 results are presented in accordance with theses as follows;

- demographic information and response rate
- impact on daily life
- patients' views of the PICC-line experience
- chapter summary.

Data are presented initially in summary form followed by more detailed analysis of specific aspects of the data. Data were analysed using confidence interval estimation to determine which questionnaire results were likely to be representative of the population represented by the sample in this study (see 3.4.4). This analysis showed which views regarding aspects of living with a PICC line were most likely to be held by MdG PICC-line patients and thus allowed the study aims to be met.

5.3.2 Response rate

A total of 69 respondents who met eligibility criteria (see 4.11) were approached to take part in Phase 2 of the study. There were three outright refusals: one declined on the grounds of tiredness while two others offered no explanation and none was sought. Four potential respondents verbally agreed to take part in the study but failed to return the questionnaire. One recall was issued but the questionnaires remained outstanding. Thus 62 respondents completed the questionnaire, giving a response rate of 90%. The questionnaires were fully completed by most respondents with only four pieces of missing data. All respondents correctly completed the front page of the questionnaire thus fulfilling the requirements for consent. Additional comments were provided by 13 respondents in the appropriate section.

5.3.3 Demographic data

Just over half of respondents were male and the majority of respondents were aged between 60 and 79 years. Most lived within 20 miles of the unit and found the unit easy to get to. The biggest majority did not know what a PICC line was prior to insertion and most had required only one PICC line. The average length of time with a PICC line in situ on completion of the questionnaire was 11 weeks.

Table 2: Summary of demographic data

Sex	Male: 54.8% (n=34) Female: 45.2% (n=28)
Age	18 - 59 years: 32.3% (n=20) 60 - 79 years: 62.9% (n=39) 80 + years: 4.8% (n=3)
Distance travelled from home to chemotherapy day unit	< 20 miles: 54.8% (n=34) > 20 miles: 45.2% (n=28)
Easy or difficult to get from home to chemotherapy day unit	Easy: 72.6% (n=45) Difficult: 27.4% (n=17)
Knew what a PICC line was prior to insertion	Yes: 8.1% (n=5) No: 79% (n=49) Can't remember: 12.9% (n=8)
How many PICC lines required for this course of treatment	1: 75.8% (n=47) 2: 22.6% (n=14) 3 or more: 1.6% (n=1)
Length of time PICC line in situ on completion of questionnaire	Mean: 11 weeks Range: 8 – 17 weeks

5.3.4 Impact on daily life

To determine which aspects of living with a PICC line caused patients most difficulty, respondents were asked to state the level of difficulty (see 4.12.2) they experienced with a PICC line in situ for a number of daily life activities (DLAs). On statistical advice the responses for 'about the same' and 'a little more difficult' were grouped together for analysis as it was assumed the resulting impact on daily life would be comparable. Respondents were also asked to indicate activities that were 'not applicable' to them, i.e. those they did not do prior to PICC-line insertion; for example, not everyone looks after children or drives a car. Space was provided for respondents to list any additional activities they were experiencing difficulty with which five respondents added to.

Table 3 below summarises respondents' reported level of difficulty for each DLA and is ranked for 'greatest reported difficulty'. The majority of respondents did not experience undue difficulty with most DLAs with the PICC line in situ. Only hair washing (n=35, 57.4%) and showering (n=25, 56.8%) were perceived to be 'a lot more difficult' by a majority of respondents although a sizeable minority (n=26, 44.1%) found bathing a lot more difficult. Shopping and dressing appeared to be minimally disrupted.

Table 3: Degree of difficulty carrying out DLA with PICC line in situ

Daily life activity	About the same/a little more difficult n = 62 (%)	A lot more difficult n = 62 (%)	Can't do because of the PICC line n = 62 (%)	Not applicable n = 62 (%)
Washing hair	26 (42.6)	35 (57.4)	0	1 (1.6%)
Showering	13 (29.6)	25 (56.8)	6 (13.6)	18 (29.0%)
Bathing	32 (54.2)	26 (44.1)	1 (1.7)	3 (4.8%)
Sleeping	45 (72.6)	17 (27.4)	0	0
Shopping	53 (85.5)	9 (14.5)	0	0
Dressing	54 (87.1)	8 (12.9)	0	0
Hobbies	37 (84.1)	5 (11.4)	2 (4.5)	18 (29.0%)
Driving	33 (80.4)	4 (9.8)	4 (9.8)	21 (33.9%)
Washing myself	56 (90.3)	6 (9.7)	0	0
Cooking*	50 (92.6)	4 (7.4)	0	7 (11.3%)
Housework	54 (93.1)	4 (6.9)	0	4 (6.5%)
Childcare*	24 (96.1)	1 (4.0)	0	36 (58.1%)
Relaxing	58 (96.7)	2 (3.3)	0	2 (3.2%)

* missing data = 1

Further analysis was carried out to determine the statistical significance of the results. Confidence intervals (CIs) for the population proportions reporting a 'lot of difficulty' were calculated to identify which DLAs the population in this study experienced most difficulty with.

As can be seen from the CIs in Table 4 below, a majority of patients in this study were likely to find showering, washing hair and bathing a lot more difficult with the PICC line in situ. While cooking, housework and relaxing were still statistically significant, fewer numbers were affected. In addition, although a minority of respondents reported a lot of difficulty sleeping, the CIs showed that as many as 40% of the population in this study experienced a lot of difficulty sleeping.

Table 4: Daily life activity reported as a lot more difficult

Daily life activity	Number performing activity pre-PICC line insertion n = 62	Number reporting 'a lot more difficulty' post-PICC line insertion n = 62	95% confidence interval n = 62
Showering	44	25	(41%, 72%)
Washing hair	61	35	(44%, 70%)
Bathing	59	26	(30%, 58%)
Sleeping	62	17	(16%, 40%)
Shopping	62	9	(7%, 26%)
Dressing	62	8	(5%, 24%)
Hobbies	44	5	(4%, 24%)
Driving	41	4	(3%, 23%)
Washing myself	62	6	(4%, 20%)
Childcare	25	1	(0.1%, 20%)
Cooking	54	4	(2%, 18%)
Housework	58	4	(2%, 17%)
Relaxing	60	2	(0.4%, 11%)

It was not useful to perform CIs for those reporting the DLA as unable to be done with a PICC line in situ as the raw data numbers were too small (see Table 3) for meaningful statistical analysis.

Overall, these findings suggest that while PICC-line patients experienced a degree of difficulty with all DLAs, only a few DLAs were a lot more difficult for the majority of patients in this study. There was little evidence to suggest that the DLAs were unable to be carried with a PICC line in situ, except in very few instances. However, a large number of PICC-line patients in this study experienced a lot of difficulty keeping clean through either bathing or showering and hair washing. Furthermore, whilst most respondents reported only minimal disruption to sleeping, the CI demonstrated that as many as four in 10 MdG PICC-line patients in this study experienced a lot of difficulty sleeping with a PICC line in situ.

5.4 Patients' views on the PICC line experience

Patients' views were sought towards aspects of the PICC line experience based on the thematic analysis of the Phase 1 interview findings. Possible responses were agree (A), strongly agree (SA), neither agree nor disagree (N), Disagree (D) or strongly disagree (SD). On statistical advice, the sample data responses for 'agree' and 'strongly agree' were grouped and the responses for 'disagree' and 'strongly disagree' were grouped.

5.4.1 Responsibility/coping at home

Table 5 below summarises the responses to the responsibility/coping at home statements. The majority of respondents felt well supported during the experience (n=59, 95%) and were happy to take responsibility for their PICC line (n=39, 64%). Similarly most respondents felt that the PICC line had made their chemotherapy easier to get (n=46, 74%), gave them independence (n=45, 73%) and felt relaxed at home with their PICC line (n=45, 73%).

Table 5: Patients' views on responsibility/coping at home with the PICC line

Statement	Agree/ strongly agree	Neither agree nor disagree	Disagree/ strongly disagree
	n=62 (%)	n=62 (%)	n=62 (%)
There is plenty of help and support for people with PICC lines	59 (95%)	1 (2%)	2 (3%)
I worry about the chemotherapy spilling	48 (77%)	0	14 (23%)
The PICC line has made my chemotherapy easier to get	46 (74%)	13 (21%)	3 (5%)
Having a PICC line gives me independence	45 (73%)	9 (14%)	8 (13%)
I am relaxed when I am at home with my PICC line	45 (73%)	6 (9%)	11 (18%)
I worry that things could go wrong with my PICC line	42 (68%)	0	20 (32%)
I am happy to take responsibility for my PICC line *	39 (64%)	11 (18%)	11 (18%)
My family/friends worry about my PICC line *	39 (64%)	4 (6%)	18 (30%)
I worry that the PICC line will fall out	38 (61%)	2 (3%)	22 (36%)
PICC lines give me extra worries when getting chemotherapy	18 (29%)	5 (8%)	39 (63%)
My life is restricted because of the PICC line	12 (20%)	9 (14%)	41 (66%)
I would have preferred to get my chemotherapy in hospital	4 (6%)	6 (10%)	52 (84%)

*missing data =1

A number of worries regarding coping with a PICC line at home were also evident. These related to the chemotherapy spilling (n=48, 77%), things going wrong with the PICC line (n=42, 68%) and the PICC line falling out (n=38, 61%). The majority of respondents (n=39, 64%) also felt that their families/friends worried about their PICC line.

Thus the summary data showed clear majority views and a range of issues where there was less consensus. The data were explored in more depth using CI estimation to determine which views were most likely to be held by the population represented by the sample. The differences between the CIs for agree/strongly agree and disagree/strongly disagree were calculated to show the areas of statistical significance.

As can be seen in Table 6, statistically significant differences were found between the agree/strongly agree and disagree/strongly disagree responses for all statements. However the size of the effect and thus the clinical relevance of the findings varied.

Table 6: CI analysis of differences between patients' views on responsibility/coping at home with a PICC line

Statement	A/SA	D/SD	95% CI
There is plenty of help and support for people with PICC lines	59	2	(83%, 100%)
I worry about the chemotherapy spilling	48	14	(33%, 76%)
The PICC line has made my chemotherapy easier to get	46	3	(55%, 83%)
Having a PICC line gives me independence	45	8	(42%, 78%)
I am relaxed when I am at home with my PICC line	45	11	(35%, 74%)
I worry that things could go wrong with my PICC line	42	20	(11%, 59%)
I am happy to take responsibility for my PICC line *	39	11	(26%, 66%)
My family/friends worry about my PICC line *	39	18	(11%, 58%)
I worry that the PICC line will fall out	38	22	(1%, 50%)
PICC lines give me extra worries when getting chemotherapy	18	39	(-56%, -11%)
My life is restricted because of the PICC line	12	41	(-67%, -26%)
I would have preferred to get my chemotherapy in hospital	4	52	(-91%, -63%)

95% confidence intervals for population proportion A/SA minus population proportion D/SD for responsibility/coping at home statements.

n=62

*missing data = 1

In keeping with the summary data, the statement relating to help and support for PICC-line patients had the largest majority favour (between 83% and 100%). This provides strong evidence that the population represented by the sample data were much more likely to feel well supported during the PICC-line experience than not. Furthermore, a significantly larger population proportion was likely to be happy to take responsibility for their PICC line (CI 26%, 66%).

Despite this, analysis showed discrepancies among views on the statements relating to worries when at home with a PICC line. A significantly larger population proportion was likely to disagree/strongly disagree (CI 11%, 56%) that a PICC line presented extra worries when receiving chemotherapy. Contradicting this, there was also evidence that a significantly larger population proportion agreed/strongly agreed that they worried about the chemotherapy spilling (CI 33%, 76%), something going wrong with the PICC line (CI 11%, 59%) and the PICC line falling out (CI 1%, 50%), although the size of the effect and thus the clinical relevance is potentially small for some.

A further two statements showed a significantly larger population proportion disagreeing/strongly disagreeing than agreeing/strongly agreeing. There is strong evidence that the majority of the population in this study were unlikely to view the PICC line as a restriction (CI -67%, -26%) or prefer to have chemotherapy in hospital (CI -91%, -63%) and again suggests a favourable opinion towards coping at home with a PICC line.

Overall, statistical analysis of these results showed that in the main, patients' views towards coping with a PICC line at home were generally positive although a number of worries existed. The main concern was the chemotherapy spilling. The strongest views held suggested a high level of help and support for PICC-line patients and that patients did not want to receive their chemotherapy in hospital.

5.4.2 Information giving

Table 7 summarises the responses to the information statements and demonstrates that respondents' views were inconsistent. Although the majority had a high information need (n=47, 76%) and felt this need had been adequately met (n=45, 72%), respondents also felt unable to remember the information given (n=47, 76%) and some felt some of the information was 'scary' (n=43, 69%). A small majority also believed that too much information was detrimental (n=33, 53%) and preferred not to be told about what might go wrong (n=34, 55%). Similarly, respondents were divided on whether doctors and nurses gave information because they had to and whether patients should be told everything about their PICC lines. It also appears that respondents were unprepared for the PICC line insertion and that most were uncertain or felt they had not been given the choice to have a PICC line.

Table 7: Patients' views on information giving

Statement	Agree/ strongly agree n=62 (%)	Neither agree nor disagree n=62 (%)	Disagree/ strongly disagree n=62 (%)
I like to know as much as possible about what is happening to me	47 (76%)	4 (6%)	11 (18%)
It is impossible to remember all the information you are given	47 (76%)	1 (2%)	14 (22%)
I had all the information I needed to cope with my PICC line at home	45 (72%)	3 (5%)	14 (23%)
Some of the information I was given about my PICC line was quite scary	43 (69%)	2 (3%)	17 (28%)
The information I was given about my PICC line was just right	42 (68%)	12 (19%)	8 (13%)
I do not like to be told too much about things that could go wrong	34 (55%)	12 (19%)	16 (26%)
Too much information is a bad thing	33 (53%)	10 (16%)	19 (31%)
Doctors and nurses tell you things just because they feel they have to	28 (45%)	5 (8%)	29 (47%)
Patients should be told absolutely everything about their PICC line	26 (42%)	8 (13%)	28 (45%)
I knew what to expect when the PICC line was put in	22 (36%)	8 (13%)	32 (51%)
I was given the choice to have a PICC line or not	18 (29%)	18 (29%)	26 (42%)

Since respondents' views towards some of the statements were less clear in terms of level of agreement, further analysis determined where there was a statistically significant difference between respondents' views. The differences between the CIs for agree/strongly agree and disagree/strongly disagree were again calculated to identify the opinions most likely to be representative of the population in this study.

As can be seen in Table 8, a statistically significant difference was not found between the agree/strongly agree and disagree/strongly disagree responses for all statements. Statistically significant results are presented in bold.

Table 8: 95% confidence intervals for population proportion A/SA *minus* population proportion D/SD for information statements.
n = 62

Statement	A/SA	D/SD	95% CI
I like to know as much as possible about what is happening to me	47	11	(38%, 77%)
It is impossible to remember all the information you are given	47	14	(32%, 74%)
I had all the information I needed to cope with my PICC line at home	45	14	(29%, 71%)
Some of the information I was given about my PICC line was quite scary	43	17	(19%, 64%)
The information I was given about my PICC line was just right	42	8	(37%, 73%)
I do not like to be told too much about things that could go wrong	34	16	(7%, 50%)
Too much information is a bad thing	33	19	(0.03%, 45%)
Doctors and nurses tell you things just because they feel they have to	28	29	(-26%, 2%)
Patients should be told absolutely everything about their PICC line	26	28	(-27%, 2%)
I knew what to expect when the PICC line was put in	22	32	(-39%, 7%)
I was given the choice to have a PICC line or not	18	26	(-34%, 8%)

95% confidence intervals for population proportion A/SA *minus* population proportion D/SD for information statements.

The analysis showed that in keeping with the initial frequency data, a significant majority of MdG PICC-line patients in this study wanted as much information as possible about their situation (CI 38%, 77%) and received optimal information (CI 37%, 73%) but nonetheless had difficulty remembering the information (CI 32%, 74%) and found some of the information 'scary' (CI 19%, 64%). The evidence regarding whether patients wanted to be told about what might go wrong and whether too much information was detrimental was less conclusive. Although the results were statistically significant, the wide CIs show that there is less certainty about these findings and in addition the size of the effect may be very small.

The statements which this population were as likely to agree as disagree with showed the areas where opinion was split. No significant difference was found between those agreeing and those disagreeing with the statement 'doctors and nurses tell you things just because they feel they have to' and 'patients should be told absolutely everything about their PICC line'. Furthermore, there was no statistical difference between those who felt they had been given a choice to have a PICC line and those who did not, or between those who knew what to expect when a PICC line was put in and those who did not.

Overall, statistical analysis of the results from this section of the questionnaire revealed patients' views towards the information given during the PICC-line experience were complex and at times contradictory. Whilst patients' views were generally favourable regarding the information given, a challenge for health care professionals in providing the optimal level and type of information was evident.

5.4.3 Adaptation/acceptance

Table 9 summarises the responses to the adaptation/acceptance statements and demonstrates that respondents' views were generally favourable. The majority of respondents felt that the advantages of a PICC line outweighed the disadvantages and would recommend a PICC line to other patients. Furthermore, although more help was needed at the beginning of the PICC-line experience, living with a PICC line got easier as time went on. However, a sizeable minority of respondents felt that having a PICC line was a frightening experience (n=17, 28%) and that they would never get used to having a PICC line (n=14, 23%).

Table 9: Patients' views on adaptation/acceptance with the PICC line

Statement	Agree/ strongly agree n=62 (%)	Neither agree nor disagree n=62 (%)	Disagree/ strongly disagree n=62 (%)
Having a PICC line gets easier the longer you have it	52 (84%)	3 (5%)	7 (11%)
The good things about a PICC line are more than the bad *	50 (82%)	11 (18%)	0
I would recommend a PICC line to other patients **	49 (82%)	11 (18%)	0
Patients with PICC lines need more help at the beginning	44 (71%)	11 (18%)	7 (11%)
I will do whatever it takes to get my chemotherapy	43 (70%)	4 (6%)	15 (24%)
I am frightened of needles	40 (64%)	1 (2%)	21 (34%)
I am happy to show my PICC line to anyone	30 (48%)	5 (8%)	27 (44%)
It is best to avoid crowds if you have a PICC line	29 (47%)	12 (19%)	21 (34%)
It bothers me if strangers see my PICC line	23 (37%)	5 (8%)	34 (55%)
Having a PICC line in is a frightening experience	17 (28%)	7 (11%)	38 (61%)
Having a PICC line is not the sort of thing you ever get used to	14 (23%)	5 (8%)	43 (69%)
Having a PICC line is more trouble than it is worth*	2 (3%)	10 (17%)	49 (80%)

* missing data =1, ** missing data =2

A sizeable minority (n=11, 18%) were uncertain as to whether the benefits of a PICC line outweighed the drawbacks and whether they would recommend a PICC line to another patient suggesting a level of difficulty in adapting to the experience. Furthermore, a total of 66% of respondents (n=33) were either uncertain or thought it best to avoid crowds with a PICC line in situ, again suggesting that respondents were unsure about certain aspects of life with a PICC line.

Respondents' views were mixed regarding whether they were comfortable with other people seeing the PICC line. Although 30 (48%) respondents were happy to show their PICC line to anyone, 23 (37%) were bothered by strangers seeing the PICC line and a small number were uncertain suggesting that some respondents had body-image issues with the PICC line in situ.

Unsurprisingly, the majority of respondents had a fear of needles (n=40, 64%) but it was also evident that most respondents (n=43, 70%) would do whatever it took to get their chemotherapy which suggests a degree of compliance brought on by the faith in chemotherapy treatment.

Again further analysis was carried out to determine where there was a statistically significant difference between the respondents' views by calculating the differences between the CIs for agree/strongly agree and disagree/strongly disagree. As can be seen in Table 10, a statistically significant difference between responses was not found for all statements suggesting there were areas where the frequency data did not reflect the populations' views in this study. Statistically significant results are presented in bold.

Table 10: 95% confidence intervals for population proportion A/SA *minus* population proportion D/SD for adaptation/acceptance statements.
n = 62

Statement	A/SA	D/SD	95% CI
Having a PICC line gets easier the longer you have it	52	7	(56%, 89%)
The good things about a PICC line are more than the bad*	50	0	(72%, 92%)
I would recommend a PICC line to other patients **	49	0	(72%, 92%)
Patients with PICC lines need more help at the beginning	44	7	(42%, 77%)
I will do whatever it takes to get my chemotherapy	43	15	(23%, 67%)
I am frightened of needles	40	21	(6%, 54%)
I am happy to show my PICC line to anyone	30	27	(-19%, 29%)
It is best to avoid crowds if you have a PICC line	29	21	(-9%, 35%)
It bothers me if strangers see my PICC line	23	34	(-42%, 6%)
Having a PICC line in is a frightening experience	17	38	(-56%, -11%)
Having a PICC line is not the sort of thing you ever get used to	14	43	(-68%, -25%)
Having a PICC line is more trouble than it is worth*	2	49	(-90%, -65%)

*missing data = 1

**missing data = 2

95% confidence intervals for population proportion A/SA *minus* population proportion D/SD for adaptation/acceptance statements.

In keeping with the initial summary data, this analysis provides strong evidence that a significant majority of this population saw the PICC line as a benefit and adapted positively to the PICC-line experience.

The summary data showed that almost one third of respondents found the PICC-line experience frightening. When explored in more depth, analysis showed that patients were more likely to disagree than agree that they found the experience frightening. However, the CI was wide (CI -56%, -11%) which suggests greater variability in responses and a less precise estimation of the size of the effect, meaning less certainty in predicting patients' views. Similarly, while most patients were likely to disagree that they would never get used to having a PICC line (CI -68%, -25%) again the CI is wide. These results suggest that only a minority of MdG PICC-line patients in this study found the experience frightening and struggled to adapt to life with a PICC line.

No significant difference in the population proportions agreeing and disagreeing were found for three of the statements. This means this population were as likely to agree as disagree with the statements and shows where there is uncertainty regarding patients' views towards that aspect of the experience. No significant difference was found between those agreeing and those disagreeing that they were troubled by others seeing their PICC line suggestive of a negative impact on body image for some patients. Furthermore, opinion was split as to whether it was best to avoid crowds with a PICC line in situ suggestive of uncertainty about this aspect of the experience and a need to provide clearer information regarding this.

Overall, statistical analysis of the results from this section of the questionnaire revealed that patients held generally favourable views towards adapting to a PICC line being in situ and showed a high degree of acceptance of the situation. Patients viewed the benefits of PICC lines to outweigh the drawbacks and would recommend a PICC line to other patients which again suggests a positive adaptation to the experience. However, a small number of patients may not adapt so easily to what can be a frightening situation which suggests that additional help and support is required for some.

5.4.4 Additional comments

Space was provided at the end of the questionnaire for respondents to add any additional comments about their PICC-line experience. Additional comments were provided by 13 respondents.

A number of the comments were not directly related to the PICC line experience for example; complaints about car parking and hospital facilities. Comments made relevant to the study were summarised as benefits and drawbacks.

Patients' reported benefits of having a PICC line were;

- receiving home chemotherapy as opposed to being in hospital
- the reduced need for venepuncture and cannulation with a PICC line in situ
- the ease of chemotherapy administration
- the excellent care received.

Patients' reported drawbacks associated with the PICC line were;

- attachment of the chemotherapy pump to the PICC line exacerbated difficulties with DLAs
- restricted intimacy with partner for fear of damaging the PICC line
- visibility of PICC line, especially in the summer months
- non-specialist staff unfamiliarity with PICC lines.

These comments echoed some of the findings from both the interviews and the questionnaires but did not add any new themes to the study findings.

5.5 Chapter key messages

This study's results show that overall, patients largely viewed PICC lines as a benefit rather than a burden when receiving MdG ambulatory chemotherapy. The key findings were;

- most patients experienced only minimal disruption to daily life activities with a PICC line in situ
- patients' views towards the PICC-line experience were largely favourable and a number of benefits associated with having a PICC line were reported
- a number of concerns regarding coping at home with a PICC line were evident however patients generally adapted well to the experience
- patients' views towards the information received during the PICC-line experience were complex and at times incongruent
- patients would not prefer to have their chemotherapy in hospital.

CHAPTER SIX - DISCUSSION

6.1 Introduction

This study was conducted to explore the impact of a PICC line on patients receiving ambulatory chemotherapy in response to the author's observations that patients were not being adequately prepared for the experience of ambulatory chemotherapy. The research objectives were developed to determine which aspects of living with a PICC line caused patients the most difficulty and what the important issues were for patients. By discovering this, nurses would be better placed to prepare patients for the experience of living with a PICC line whilst receiving ambulatory chemotherapy and to pro-actively manage each care episode.

The study results and the extent to which the study aims were met are discussed in this chapter. The limitations of the study are also presented. The main aim of the study was to explore the views of patients receiving MdG cytotoxic chemotherapy via a PICC line in order to contribute to the current understanding and research on the subject matter. The objectives of the study were:

1. To determine which aspects of living with a PICC line caused patients most difficulty.
2. To explore patients' views towards the PICC-line experience.
3. To determine if patients view PICC lines as a benefit or a burden when receiving cytotoxic chemotherapy.

6.2 Aspects of living with a PICC line that cause patients the most difficulty

This study's results demonstrated that having a PICC line in situ affected the daily lives of participants in a number of ways in keeping with Dobson (2001), Cole (1999), Daniels (1996) and Thompson et al (1989) who also reported that the presence of a CVAD had the potential to impact on patients' lives in multiple ways.

Although the interview findings revealed that most patients experienced difficulty with dressing, sleeping, bathing, showering and partaking in hobbies as a result having a PICC line, when impact on daily life was assessed by the questionnaire, it was found that only minimal difficulty with most DLAs was reported by the majority of patients. This is in keeping with Gabriel (2003; 2000) and (Borst et al 1992) who found that lifestyle was relatively unaffected by the PICC line but minor disruption was reported by some patients.

The aspects of daily life that patients experienced most difficulty with were showering, hair washing, bathing and sleeping. This compares favourably with the findings of Oakley et al (2000) who reported that patients experienced most difficulty with bathing and sleeping but that

these difficulties diminished with time. In this study, generally baths were easier than showers with a PICC line in situ since the affected arm could be kept away from the water. Nonetheless, keeping clean by showering, bathing and hair washing proved difficult for most patients. These findings are important since keeping clean and sleeping are arguably among the most vital of DLAs and disruption of them could lead to additional physical and emotional upset. Oakley et al (2000) also reported difficulty dressing in half of their study patients however this finding was not upheld in this study. It may be that since the patients in this study had the PICC line in situ for a longer period of time, that is a mean of 11 weeks at time of questionnaire completion compared with four weeks in Oakley et al's study, that any initial difficulties with dressing had been resolved.

Despite this, it is a concern that a range of difficulties were experienced by participants at the start of the PICC line journey when they were still struggling to come to terms with a potentially fatal relapse of cancer and the commencement of a new chemotherapy regimen. For example, the necessity to purchase new or modify existing clothing to accommodate the PICC line was a potential stressor that the patients could have done without at such a difficult time. Similarly it is essential that patients who may already be fatigued because of their advanced disease or as a result of their chemotherapy get adequate rest and sleep at night. The number of patients who experienced difficulty sleeping with a PICC line in situ was a concern and perhaps more practical information relating to sleeping positions with a PICC line is needed.

Interestingly in this study, the participants' actions did not always mirror the advice they had been given. Interview participants often stated that although they had been advised that a certain activity was allowed, they nonetheless opted not to carry out that activity. An example of this is the advice given re bathing and showering: participants acknowledged being told that it was "alright" if the PICC line and dressing got wet but to avoid completely soaking the PICC line yet they still preferred to avoid the PICC line getting wet at all, in one case by not bathing or showering for the full duration of the PICC line being in situ. These fears of soaking the PICC line may part explain the difficulties with bathing, showering and hair washing reported by questionnaire respondents.

Similarly, participants reported they were advised that hobbies such as golf and bowls were safe to do but nonetheless they decided not to engage with whilst the PICC line was in situ. Four interview participants stated that they did not feel able to partake in certain hobbies with a PICC line as they feared damaging it or themselves in some way. The questionnaire results also revealed that a small number of patients felt unable to engage in hobbies (n=2) or drive (n=4) as a result of the PICC line being in situ. The only activity which is medically contra-indicated

with a PICC line in situ is swimming (Philpot and Griffiths 2003). Therefore it would appear that in some instances the participants remembered the advice given but chose to disregard it and therefore the impact on daily life was arguably more than it would otherwise have been. This incongruence between advice received and behaviour exhibited also suggests that some difficulties experienced in the day to day lives of PICC-line patients related to the information given and is further explored in the next section.

6.3 Patients' views towards the PICC line experience

6.3.1 Information giving

This study's results suggest that participants found it difficult to cope with the amount of information given to them around the time of PICC line insertion and that some of the information given was frightening and/or unhelpful. This is not surprising when one considers the amount and type of information that these patients require to be given around this time and which includes; details of the recurrence of cancer, prognostic outlook, schedule of appointments, chemotherapy regimen and side effect management, and PICC-line information.

A key finding from the literature review was that although patients may express a wish to receive as much information as possible regarding their treatment/care (Knowles et al 1999; Graydon et al 1997; Meredith et al 1996), they nonetheless struggle to cope with the volume of information given (McCaughan and Thompson 2000). This study also found that although patients wanted and received information, most found the information given overwhelming and impossible to remember. The interviews revealed there was a perception among some patients that health care professionals give information because of a need to tell patients everything in today's health care climate to avoid litigation, which suggests that patients could not see value in some of the information that was being given. Analysis of the questionnaire results showed that opinion on this was split and therefore no firm conclusions can be drawn from this study. However it remains evident that a number of patients with PICC lines felt information was being mass produced rather than individually tailored to their needs.

Furthermore, although patients reported a high information need, most also wished to avoid excessive information about what might go wrong. This suggests that the type of information supplied to patients is not necessarily in keeping with that which is required and supports the earlier findings of Skalla et al (2004), Elf and Wikblad (2001), McCaughan and Thompson (2000), Sitzia and Wood (1998b) and Fernsler (1986). These findings when considered in light of the difficulties reported in coping with DLAs with a PICC line in situ (see 6.2) further

suggest that patients need more information about the practicalities of living with a PICC such as advice on dressing, sleeping, washing and so forth and less on the potential problems associated with PICC lines.

Many of the difficulties experienced by participants in this study appear to have been heightened by the complex nature of the information giving around the time of PICC line placement. The dichotomy is that whilst much information must be given to patients to prepare them for and enable them to cope with a PICC line, the volume of the information and the gravity of the situation means that they are often unable to comprehend or remember all the information. The literature on information giving to chemotherapy patients showed that patients may fail to retain information in stressful situations (McCaughan and Thompson 2000; Knowles et al 1999) and that overwhelming patients with information can add to feelings of fear, confusion and anxiety (McCaughan and Thompson 2000). Paradoxically, the provision of information can also reduce anxiety and distress (Sitzia and Wood 1998a) if it is timely and appropriate.

Participants in Phase 1 of this study commented that they were given a great deal of detail regarding the actual intricacies of the insertion procedure yet almost half felt unprepared when it happened. This was in keeping with the questionnaire results which showed there was no significant difference between the number of patients who knew what to expect when the PICC line was put in and those who did not and compares with the findings of Goossens et al (2001), Daniels et al (1996) and Borst et al (1992) who found that patients felt unprepared for the insertion experience despite the information given pre-insertion.

The questionnaire results also showed that a considerable number of patients in this study did not feel they had been given the choice to have a PICC line or not. This is a concern since patients are required to provide written consent prior to PICC-line insertion yet no evidence was found to suggest that patients generally felt prepared for the event and it may be that patients felt they had no option but to accept a PICC line. Cole (1999) and Gabriel (2003) stated that perceived choice in device selection/method of administration can have a positive impact on how readily patients accept a PICC line or other CVAD. However in this study the lack of perceived choice in having a PICC line did not appear to influence acceptance of the device. Nonetheless AETMIS (2004) and Rowe et al (2002) stressed the importance of patient choice in decision making regarding chemotherapy administration in the ambulatory setting to avoid those less able or reluctant for home treatment being coerced into accepting. It may be however, that the growing demand for chemotherapy (Twelves 2001) and the associated

increase in out-patient/ambulatory chemotherapy (Young and Kerr 2001; Sitzia and Wood 1998a) dictates that PICC lines become standard and patient choice is diluted as a result.

The implications of this for practice are fairly considerable: as the literature review has repeatedly shown, new and more efficient ways of giving patients complex and voluminous information are required if patients' needs are to be adequately addressed. There remains a difference between health care professionals' and patients' perceptions of what information is considered 'essential'. Furthermore, as Marc (2005) stressed, the increase in ambulatory chemotherapy requires that patients and their carers involved in ambulatory chemotherapy are adequately prepared for the experience to enable them to cope at home, as explored in the next section. Marc (2005) and AETMIS (2004) stressed the importance of providing information to patients and their carers when undergoing ambulatory chemotherapy although it would appear that this is not being adequately provided. When considered in light of the problems highlighted by this study regarding information giving in this group of patients, it may be that the information is being given but not understood or retained by patients

6.3.2 Responsibility for the PICC line/coping at home

In this study, participants generally coped well at home with their PICC lines and most appeared happy to take on the additional responsibility. There was an acceptance that although having a PICC line impacted upon their daily lives, the bonus of not being hospitalised to receive chemotherapy outweighed the drawback. This was in keeping with Chernecky (2001) and Borst et al (1992) who found that the advantages associated with a CVAD in the home setting more than compensated for the difficulties. Several of the participants in Phase 1 of this study also commented that the PICC line gave them freedom which was particularly important now that they were living with a terminal illness. Similarly, the questionnaire results showed that the majority of patients felt the PICC line gave them independence and made chemotherapy administration easier and supports the findings of Goossens et al (2001) whose study patients reported ease of chemotherapy administration and increased freedom during administration with a CVAD in situ.

Despite the overall positive views towards coping at home with a PICC line, a number of concerns were evident, again in keeping with the findings from the literature review. The most common perceived fears in this study were of the chemotherapy spilling, malfunction of the PICC line or the PICC line falling out. One of the key findings of AETMIS (2004) was that concerns over safety for patients on home therapy were a significant source of distress to both the patient and their informal carers. Similarly, Dougherty et al (1998) stated that treatment in the home setting can be a daunting experience and can place a significant pressure on patients

and families. Dougherty et al (1998) also stated that some patients are unwilling to take on this added responsibility and may opt to have treatment as an in-patient instead. Although a desire for in-patient treatment was not evident in this study, patients felt that their families/friends worried about the PICC line. It may be that PICC-line patients' friends and families had similar worries concerning the PICC line and therefore also require a level of help and support to aid their coping.

Interestingly, Phase 1 of this study showed that these concerns were very much a fear of what might happen as very few participants had actually experienced any technological difficulty with the PICC line or the chemotherapy pump at home.

Nonetheless, the fear was very real for participants to the extent that they questioned how prepared they would be to deal with such a malfunction should one occur and was tied in with the participants' perceptions that they required to stay close to specialist help at all times. This was a common finding from the interviews particularly in those who were geographically distant from the specialist centre. Several of the participants lived less than five miles from the specialist centre and commented that if they had a problem, they could 'pop up' and see a health care professional, although again none had actually needed to do this. Those who lived further a field did not have this luxury and appeared to worry more about malfunction and what to do in the event of something going wrong. The demographic data from the questionnaire similarly suggested that ease of getting to the specialist unit may influence the perceived level of help and support available. Those who live fairly close by and/or find it easy to get to the specialist unit may feel that more help is readily available.

The difficulties experienced by some participants when they required assistance at a health-care facility other than the specialist centre may have added to these fears. A number of participants came into contact with health care professionals who had no skills or experience in dealing with PICC lines which served to further undermine the participant's confidence. The reluctance of non-specialist health care personnel to access a CVAD was also highlighted as a key disadvantage in Chernecky's (2001) study. This suggests that the training and education of non-specialist staff that may come into contact with devices such as PICC lines is crucial to the patient's care. However, it must be remembered that this study was conducted when PICC lines were not commonly used in the UK and therefore the majority of health care staff would be unfamiliar with them. As the number of PICC lines continues to increase, it is likely that more staff will become adept in PICC-line care however it remains a key consideration when developing PICC-line services.

Despite the fears outlined, generally most patients were happy to take on the added responsibility associated with the PICC line in keeping with Rowe et al (2002) and Thompson et al (1989). Christopoulou (1993) found that the degree of support available in the home setting was a crucial factor in how readily patients accepted home chemotherapy. The patients in this study felt very well supported therefore it may be that they felt able to cope at home with the PICC line despite the underlying fears. Furthermore, there was strong evidence in this study that patients did not want to receive their chemotherapy in hospital which may have influenced their acceptance to take on the responsibility for the PICC line. However a desire to be treated external to the hospital setting does not necessarily imply a willingness or competence to take on board the added responsibility necessary. This study has also shown that in keeping with AETMIS (2004), Dobson (2001), Cole (1999), and Dougherty et al (1998), not all patients can be assumed to have the necessary competence and confidence to cope at home with a PICC line or other CVAD, although it is likely that this will be true of only a minority of patients.

6.3.3 Adaptation/acceptance

The majority of participants in this study were able to adapt to the experience of living with a PICC and stated that they would recommend a PICC line to other patients. This concept of adaptation and acceptance has been previously demonstrated in other studies investigating patients' experiences with a variety of CVADs. Daniels (1996) in her overview of the impact of a skin-tunnelled CVC on patients with cancer concluded that they had less impact than she had previously imagined and that patients adapted well to the experience. Later work by Gabriel (2003 and 2000), Rowe et al (2002) and Oakley et al (2000) endorsed these findings.

The potential advantages associated with a PICC line appear to be factors in helping patients accept PICC lines. Interview participants in this study commonly commented on the advantage of not requiring multiple peripheral venous cannulations in order to receive chemotherapy which was highlighted in the literature review as being one of the most prominent positive indicators for acceptance of a CVAD (AETMIS 2004; Gabriel 2003; Rowe et al 2002; Chernecky 2001; Goossens et al 2001; Bow et al 1999; Daniels 1996; Borst et al 1992; Claessen et al 1990). Similarly the questionnaire results showed that the majority of patients had a fear of needles and that the PICC line had made chemotherapy administration easier so this positive indicator is to be expected. Many cancer patients require intensive and/or lengthy chemotherapy regimens using irritating agents which can irreparably damage peripheral venous access, and may have or develop needle phobia. Therefore insertion of a PICC line earlier on in the chemotherapy journey may facilitate chemotherapy administration for a number of patients. Indeed, it may be that this advantage alone merits the insertion of a PICC line for some patients.

There also appeared to be an almost philosophical belief amongst participants of accepting the hand they were dealt so to speak. Interview participants talked of "just getting on with it" and of having "no option but to accept it" as this was the reality of their situation. The questionnaire responses also indicated that the majority of patients would do whatever was necessary to receive chemotherapy therefore it may be that the PICC line was accepted as simply being a necessary part of this process.

It was also evident from this study that despite the initial difficulties experienced, patients felt that the benefits in having a PICC line outweighed the drawbacks. The literature review had demonstrated that the length of time a CVAD was in situ could both positively and negatively impact on patient acceptance (Dobson 2001) although in this study, participants generally felt more positive as time went on. It was apparent that more help was required at the start of the PICC-line experience which again has implications for the support of PICC-line patients and is discussed in section 7.2.

This study's findings on how a PICC line impacted upon patients' body image were inconclusive. It would appear that to some patients, the PICC line represented a 'badge' of illness that they were unhappy to reveal to others whilst other patients had no such concerns. The literature review equally demonstrated mixed findings on how a PICC line or other CVAD may impact on patients' body image. Dobson (2001), Borst et al (1992) and Thompson et al (1989) reported a potential negative impact on body image although Daniels (1996) failed to reveal a link between negative body image and the presence of a CVAD.

Interestingly, Oakley et al (2000) found that this may be more of an issue when the chemotherapy pump is attached and during hot weather when the PICC line/pump is more difficult to conceal under clothing. It will be recalled that section 5.9.10 detailed additional comments provided on the patient questionnaires. A small number of patients indicated that attachment of the chemotherapy pump exacerbated difficulties with DLAs and that visibility of the PICC line during the summer months was a drawback. Since the main questionnaire data collection was carried out during the winter months, it may be that most participants had not experienced living with a PICC line during the summer therefore had been less conscious of the visibility of the PICC line/pump under winter clothing. It is feasible that more patients would have reported unease with others seeing the device if data collection had taken place during warmer weather.

Another noteworthy finding from this study was that many participants perceived they must avoid crowded areas such as shopping centres for fear of the PICC line being damaged. This

was apparent from both the interview findings and questionnaire results. Oakley et al (2000) and Daniels (1996) also found that patients had a fear of being in a crowd for the same reasons. This is an area of concern as it could potentially lead to patients withdrawing from certain social situations that they may have otherwise enjoyed, arguably even more of a concern with terminally ill patients who do not have the promise of future health to look forward to.

Overall, this study showed that most patients adapt well to the experience of having a PICC line and view a PICC line as a benefit rather than a burden. However, almost one third of patients felt that having a PICC line was frightening and a sizeable minority also felt that they would never get used to having a PICC line. This is in keeping with one of the key findings from the literature review: whilst the insertion of a CVAD such as a PICC line to undergo ambulatory chemotherapy is acceptable to the majority, there is a minority of patients who struggle with the situation and who may require more individualised help and support to adapt to the experience.

6.4 Summary of discussion

The results from this study show that overall the participants generally viewed the PICC line as a benefit rather than a burden and coped well with the PICC line experience although a number of difficulties or challenges arose.

The aspects of daily life that PICC-line patients experienced most difficulty with were showering, hair washing, bathing and sleeping. It was evident that patients needed more help at the beginning of the experience therefore ways of facilitating early adaptation may reduce the number of worries or concerns that patients carry with them as time goes on. Overall, the majority were able to adapt to the changes required and found the experience easier as time progressed. To this extent, familiarity with the PICC line brought confidence and an acceptance of it as a necessary part of their overall chemotherapy care.

A number of advantages in having a PICC line were reported by participants and included the reduced need for venepuncture and cannulation, the ease of chemotherapy administration and not requiring hospital admission to receive chemotherapy. Despite the generally positive views, a number of concerns associated with having a PICC line in the ambulatory setting were also identified and were a concern as they had the potential to impact negatively on the lives of patients and also because they highlighted the uncertainties patients with PICC lines faced on a daily basis. Arguably the area of greatest concern related to information giving in relation to a PICC line.

It would appear from this study that good, appropriate information giving when a patient requires a PICC lines remains a challenge. This study along with others has shown that whilst PICC-line patients have a high information need, the information supplied is not necessarily in keeping with that which they would find helpful. Interestingly, this study showed that some of the difficulties experienced by patients related more to the attached chemotherapy pump than the PICC line itself. Since not all PICC-line patients will require a pump attachment, it is likely that the information needs of different groups of PICC-line patients will vary.

6.5 Study robustness

The concepts of validity and reliability and how they relate to both qualitative and quantitative methodologies were discussed in Chapter three.

Overall, the mixed methods approach added to the validity of the study findings since the questionnaire used in Phase 2 was developed from the qualitative data collected in Phase 1 and from the findings of previous research carried out into the patient-impact of PICC lines or other CVADs. In addition, the use of an expert panel to select the items for inclusion in the questionnaire and the full consideration of both positive and negative statements from the interview transcripts meant that the content was both relevant and served as a true reflection of the participants' realities and therefore the questionnaire demonstrates both face and content validity.

It was not possible to demonstrate criterion validity (see 3.5) in this study since no other previously validated tool measuring the same variables exists. Similarly, construct validity (see 3.5) could not be achieved as no existing research based evidence was available which could be used to formulate a hypothesis. Further use of the questionnaire could allow external validity to be demonstrated in the future.

Reliability is equivalent to consistency (see 3.5) and methods of increasing consistency in interviews were the use of the same interviewer; adherence to the interview schedule and taking a neutral stance during interviews. Furthermore, the questionnaires used in Phase 2 of the study were structured and all distributed in the same way which gives consistency.

Other methods of demonstrating reliability include test-retest reliability and inter-observer reliability (Bryman 2004; Gibbon 1998). However these were inconsistent with the study design. Furthermore, the use of a statistical test such as Cronbach's alpha to measure internal reliability was also considered inappropriate since the questionnaire was not designed to

measure one underlying attitude towards a PICC line but rather to assess respondents' views on a number of PICC-line associated themes. However, it is recognised that difficulties exist in determining the reliability of Likert-type scales as the views, opinions or attitudes measured by them are dynamic and there is no 'true' answer to the questions posed (Oppenheim 1992). This means that many researchers are unable to apply rigorously all the principles of reliability in a given study (Bryman 2004) and the most important considerations are the purpose of the instrument and the claims made from the results (Oppenheim 1992).

The purpose of the instrument used in this study was to explore the views of patients receiving MdG cytotoxic chemotherapy via a PICC line to contribute to the current understanding and research on the subject matter. The study design maximised how representative of the target population the data was therefore it is claimed that the results of the study are valid and representative of the population at the time of the study and in the place where the study took place. Whilst these results may be transferable to other comparable oncology/PICC-line units, it is not possible to claim that the results are representative of the PICC-line population generally.

6.6 Researcher reflexivity

The author has an extensive background in cancer and chemotherapy nursing and had carried out much reading in relation to the study subject matter therefore it stands to reason that a number of opinions regarding patients with PICC lines were already formed. Indeed, one of the initial prompts for carrying out the study was the observation that PICC lines posed an additional burden on patients and furthermore, the literature review carried out during the study had highlighted the potential added difficulties for patients. It was therefore crucial that self-reflection was practised to reduce potential interviewer bias or bias in the qualitative data analysis. Thus in Phase 1 of the study, analysis of the data was deferred until all interviews were completed and vigilance in including both positive and negative comments made in relation to PICC lines was taken when analysing the interview findings. A full list of the important themes from the interview data was circulated to the expert panel involved in selecting items for inclusion in Phase 2, and as can be seen from the appendices, included a range of both positive and negative comments towards PICC lines.

Included in the field notes were comments made regarding whether or not the participants were experiencing the difficulties anticipated. Thus by continually reflecting on why decisions were made to include or omit potential data, the author can demonstrate that she has included all the pertinent themes and not just those which would have confirmed her initial concerns. Examination of the initial interview important sentences, end list of themes and completed

questionnaire data demonstrate that the researcher has made every attempt to obtain a true picture of the experience including both positive and negative aspects.

As a novice researcher, undertaking this study resulted in a great deal of personal learning both in relation to the study subject matter and the research process. With regard to the impact of a PICC line on the patient receiving MdG ambulatory chemotherapy, the study demonstrated that the author's initial concerns while well-intentioned were not fully founded. This study showed that most patients adapted well to the experience with only a small number of patients experiencing major difficulties. Prior to the study, it was the author's belief that a larger number of patients were experiencing considerable difficulty when in fact the results show this not to be the case. It may be that when dealing with chemotherapy patients, the more challenging cases are the more memorable and hence the importance of using research evidence rather than personal experience to influence practice and develop policy is reinforced.

An in-depth understanding of the research process has been gained through the undertaking of this study. The triangulated design allowed the opportunity to experience both qualitative and quantitative research processes although it has also added to the challenges in carrying out the study. One surprise was the relative ease of obtaining ethics approval for both phases of the study although it is appreciated that this may not always be the case. Other key areas of learning have been the importance of having specific research aims and to exercise caution when interpreting the results from the study. The author believes the learning that has occurred as a result of undertaking this study will influence future personal research practice and will also help in supporting other researchers.

6.7 Limitations of the study

The main limitation of this study is that the results can only be interpreted against the sample frame, i.e. MdG patients receiving ambulatory chemotherapy at the oncology unit where data collection took place. The limitations in study robustness (see section 6.7) mean that the experiences and views of other PICC-line patients could differ according to where and when they received their chemotherapy. To generalise the conclusions from this research to other groups of PICC-line patients would require further research, for example a multi-centred study sampling PICC-line patients undergoing a variety of chemotherapy regimens.

The interview data analysis also had limitations as the author was an inexperienced researcher undertaking this process for the first time. This was addressed by transcribing the interviews verbatim to insure that all possible statements of note were pulled out from the data. The use of the reflexive approach as described in section 6.8 meant that all the interview themes were considered by the expert panel to insure accuracy prior to questionnaire construction.

Nonetheless, it is possible that some themes were missed by the researcher which may have been picked up if an independent researcher had reviewed some of the interview transcripts.

Another limitation was apparent in the questionnaire content. The interviews revealed that participants often stated that some of the problems they had living with a PICC line related more to the chemotherapy pump than the PICC line itself. Several questionnaire respondents also commented on this and on reflection, it would have been helpful if the questionnaire had been designed to specifically address this. In the event, it was not possible to ascertain which difficulties were caused by the PICC line and which were caused by the chemotherapy pump. This has implications for practice as not all PICC-line patients will require a chemotherapy pump and would require further research to address.

CHAPTER SEVEN - CONCLUSION AND RECOMMENDATIONS

7.1 Conclusion

The study was designed to explore the views and experiences of patients receiving ambulatory MdG chemotherapy via a PICC line. The results demonstrate that the majority of PICC-line patients held favourable views towards having a PICC line and adapted well overall to the experience. The study highlighted that the main challenges for patients centred on showering, bathing, hair washing and sleeping and that a number of worries remained with them during the time the PICC line was in situ. Furthermore, the challenges in providing optimal information to this group of patients were evident as patients reported some of the information given to them was unhelpful and at times frightening. Nonetheless, the vast majority of patients adapted well to the experience and viewed the PICC line as a benefit rather than a burden.

The study results are generally in keeping with previous research into the impact of CVADs on patients in that the potential difficulties were highlighted but also that most patients coped well. The value of this study was its ability to document the specific difficulties faced by patients with PICC lines in the home environment in relation to a number of key areas. This was one of only a few studies which examined the impact of a PICC line on ambulatory patients and the findings are both important and timely as PICC-line usage continues to increase.

7.2 Recommendations

1. The current information given to patients requiring a PICC line should be reviewed locally and different methods of providing information explored.
2. Patients should be assessed formally as to their ability to cope with a PICC line at home.
3. Ways of providing maximum support at the beginning of the PICC line experience should be explored.
4. PICC lines should be considered for use in more chemotherapy patients.
5. Further research should be carried out into the specific needs of different groups of PICC-line patients.

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APPENDICES



Doreen Molloy
Chemotherapy Clinical Educator
G6&7 Mezzanine Office
G block
Western Infirmary
Glasgow G12 6NT

Tel: 0141 211 2918 e-mail: Doreen.molloy@northglasgow.scot.nhs.uk

Dd/Mm/Yy

Dear Doctor

MSc Research study "The impact of a PICC line on the patient receiving MdG ambulatory chemotherapy"

I am writing to you regarding the above study that seeks to examine the impact of PICC lines on the patients requiring them for MdG and also to discover any ways in which we can improve the overall experience. As you currently send patients for PICC line insertion, I am asking you to grant me access to your patients for the purposes of this study.

I have enclosed a copy of the research proposal, which includes details of the aims of the study, methodology, sample size, inclusion/exclusion criteria and so forth. I would draw your attention in particular to pages 11 – 15 which are perhaps the areas of most relevance to you. Full attention will be paid to all necessary ethical requirements to insure that no patients are inappropriately approached nor any emotional upset or inconvenience placed upon them.

I would be grateful if you would consider this request and let me know if you have any objection to any of your patients being approached to take part in this study.

Please contact me if you have any questions regarding this request.

Thank you for taking the time to consider this request.

Yours sincerely



Doreen Molloy
Chemotherapy Clinical Educator
G6&7 Mezzanine Office
G block
Western Infirmary
Glasgow G12 6NT

Tel: 0141 211 2918 e-mail: Doreen.molloy@northglasgow.scot.nhs.uk

Dd/Mm/Yy

Dear

MSc Research study "The impact of a PICC line on the patient receiving MdG chemotherapy"

I am writing to you regarding the above study that seeks to examine the impact of PICC lines on the patients requiring them for MdG chemotherapy and also to discover any ways in which we can improve the overall experience. As you are currently involved in the management of the PICC line service, I am asking you to grant me access to the service and the associated nursing staff for the purposes of this study.

I have enclosed a copy of the research proposal, which includes details of the aims of the study, methodology, sample size, inclusion/exclusion criteria and so forth. I would draw your attention in particular to pages 11 – 15 which are perhaps the areas of most relevance to you. Full attention will be paid to all necessary ethics requirements to insure that no patients are inappropriately approached nor any emotional upset or inconvenience placed upon them.

I would be grateful if you would consider this request and let me know if you have any objection to my request. Please contact me if you have any further questions.

Thank you for taking the time to consider this request.

Yours sincerely



THIS SHEET HAS BEEN APPROVED BY THE WEST ETHICS COMMITTEE

INFORMATION SHEET FOR PATIENTS/VOLUNTEERS IN CLINICAL RESEARCH PROJECT

Brief Title of Project

The impact of a PICC line on the patient receiving cytotoxic chemotherapy.

Patient's Summary

This is an information sheet inviting you to take part in a research study being carried out at the The research is being undertaken as part of a Master's degree course that the researcher is undertaking at the University of Glasgow. The purpose of this study is to find out more about the ways in which the PICC line (which was put into your arm in order for you to receive your chemotherapy) has affected your life.

We are committed to ensuring that patients have the information they need to help them cope with the experience of receiving chemotherapy through a PICC line. It is very important therefore that we are able to find out as much as we can about the experiences people have so that we can improve the information given to patients. Although you will not benefit directly from taking part in this research study, it may improve the care given to patients in the future.

You have been asked to consider taking part in this study because you have a PICC line. This would involve being interviewed by the nurse carrying out the study. The interview will take place in a room separate from the chemotherapy rooms in Hospital either during one of your planned visits or at a different time if you wish.

The interview will last approximately 30 – 45 minutes and will be tape-recorded so that the nurse carrying out the study can go over and understand what you have said. The tapes will be transcribed and all material will be destroyed at the end of the study.

During the interview, you will be asked questions about how your life has been since the PICC line was put in. You will also be given an opportunity to

APPENDIX III

tell the nurse anything you feel is important regarding the PICC line. The researcher will use the information you give to produce a report on patients' experiences, which will be read by other people with an interest in this subject. Please be as honest as you can as your views are very important. Any information you might give will be anonymized and at no time will you be identified.

Please be assured that if you do not wish to participate in this study, or wish to withdraw at any time, your care will in no way be affected.

Thank you for considering this request.

If you are interested in taking part in this study and have any questions regarding this, please contact;

Doreen Molloy
Chemotherapy Clinical Educator
G6&7 Mezzanine Office
G block
Western Infirmary
Glasgow G12 6NT

Tel: 0141 211 2918

e-mail: Doreen.molloy@northglasgow.scot.nhs.uk



THIS SHEET HAS BEEN APPROVED BY THE WEST ETHICS COMMITTEE

INFORMATION SHEET FOR PATIENTS/VOLUNTEERS IN CLINICAL RESEARCH PROJECT

Brief Title of Project

The impact of a PICC line on the patient receiving cytotoxic chemotherapy.

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of the study?

The research is being undertaken as part of a Master's degree course that the researcher is undertaking at the University of Glasgow. The purpose of this study is to find out more about the ways in which the PICC line (which was put into your arm in order for you to receive your chemotherapy) has affected your life. We are committed to ensuring that patients have the information they need to help them cope with the experience of receiving chemotherapy through a PICC line. It is very important therefore that we are able to find out how the PICC line has affected your life so that we can improve the information we give to patients.

Why have I been chosen?

You have been asked to consider taking part in this study because you have a PICC line and are receiving chemotherapy. About 100 patients will be asked to participate in the study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will I have to do?

Participation in the study will involve the completion of one questionnaire. The questionnaire will be filled in after the PICC line has been in your arm for about 8 weeks. It will take

approximately 20 minutes to complete the questionnaire. A stamped, addressed envelope is included with the questionnaire for you to send it back once completed.

What are the possible benefits of taking part in the study?

Although you will not benefit directly from taking part in this research study, we hope that the information obtained will improve the care given to patients in the future.

Will my taking part in the study be kept confidential?

If you decide to take part in the study, any information you give will be kept strictly confidential. At no time will you be identified from the information you may give.

What will happen to the results of the research study?

The researcher will use the information you give to produce a report on patients' experiences, which will be read by other people with an interest in this subject. A summary of the findings of the study will also be available in Ward Again, you will not be identified in any way in the report.

What happens next?

If after reading this and thinking about your involvement you decide you want to take part, please complete the enclosed questionnaire and consent form and post back to me in the envelope provided. If you decide you do not wish to take part, you do not need to do anything else or let anyone know. If you have any questions or concerns at all about any aspect of the study, please contact (details below).

Thank you for considering this request.

Doreen Molloy
Education Department
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Glasgow G21 3AY

Tel: 0141 531 1386

e-mail: doreen.molloy@mariecurie.org.uk

WEST ETHICS COMMITTEE

FORM OF CONSENT FOR PATIENTS/VOLUNTEERS IN CLINICAL RESEACH PROJECT

Title of Project:

The impact of a PICC line on the patient receiving cytotoxic chemotherapy.

By signing this from you give consent to your participation in the project whose title is at the top of this page. You should have been given a complete explanation of the project to your satisfaction and have been given the opportunity to ask questions. You should have been given a copy of the patient information sheet approved by the West Ethics Committee to read and keep. Even though you have agreed to take part in the research procedures you may withdraw this consent at nay time without the need to explain why and without any prejudice to your care.

Consent:

I, (PRINT)

of.....

give my consent to the research procedures above, the nature, purpose and possible consequences of which have been described to me

by.....

Patient's signature..... Date

Researcher's signature.....

Ms D Molloy
Chemotherapy Clinical Educator,
Beatson Oncology Centre
Western Infirmary
Glasgow

Dear Ms Molloy

PROJECT NO: 04/157(1) (Please quote on all correspondence)
R&D No: 03ON044CAW

PROJECT TITLE: Ms D Molloy – The psychosocial impact of a PICC line on the patient receiving cytotoxic chemotherapy.

As Administrator of the West Research Ethics Committee I have considered the amendments submitted in response to the Committee's earlier review of your application on 6th January 2004 as set out in my letter dated 8th Jan 2004. The documents considered by me as Administrator were as follows:

- Letter from you dated 12th January 2004
- Amended Patient Information Sheet

As Administrator, acting under delegated authority, I am satisfied that these accord with the decision of the Committee and I have agreed that there is no objection on ethical grounds to the proposed study. I am therefore happy to give you the favourable opinion of the Committee on the understanding that you will follow the conditions as set out below:

Conditions

- You do not recruit any research subjects within a research site unless favourable opinion has been obtained from the relevant REC.

- You do not undertake this research in an NHS organisation until the relevant NHS management approval has been gained as set out in the Framework for Research Governance in Health and Social Care.
- You do not deviate from, or make changes to the protocol without prior written approval of the Research Ethics Committee except where this is necessary to eliminate immediate hazards to research participants or when the change involves only logistical or administrative aspects of the research. In such cases the REC should be informed within seven days of the implementation of the change.
- You should complete and return the standard progress report form to the REC one year from the date of this letter and thereafter on an annual basis. This form should also be used to notify the REC when your research is complete and in this case should be sent to this REC within three months of completion.
- If you decide to terminate your research prematurely, you should send a report to the REC within 15 days, indicating the reason for the early termination.
- You should advise the REC of any unusual or unexpected results that raise questions about the safety of the research.
- This Committee conforms to and abides by the ICH Guideline for Good Clinical Practice.

The project must be started within three years of the date of this letter.

Kind Regards

Yours sincerely,



Andrea H Torrie

ADMINISTRATOR - WEST ETHICS COMMITTEE



West Glasgow Ethics Committee 1

Telephone: 0141 211 6238
Facsimile: 0141 211 1920

Email: andrea.torrie@northglasgow.scot.nhs.uk

14 January 2005

Mrs Doreen Molloy
Lecturer in Cancer and Palliative Care
Marie Curie Cancer Care
Education Department
Marie Curie Cancer Care, 1 Belmont Road
Glasgow
G21 3AY

Dear Mrs Molloy

Full title of study: *The impact of a PICC line on the patient receiving cytotoxic chemotherapy.(PICC: Peripherally Inserted Central Catheter)*
REC reference number: 05/S0703/4
Protocol number:

The Research Ethics Committee reviewed the above application at the meeting held on 11 January 2005.

The Committee wished to thank you for attending the meeting to discuss your study.

The Committee only had one minor comment to make i.e. that they were of the opinion that a clinician from the Beatson should be added to the application - i.e. Prof. Cassidy or someone similar.

The Patient Information sheet should be amended as follows

- a) Under Section "What is the Purpose etc" - delete "We are committed to ensuring - direct to the end of that para". The second sentence should now read "affected your life so we can improve the information we give to patients".
- b) Under Section "What happens next" - 2nd line should read - "Please complete the enclosed questionnaire and Consent Form and post both of these back to me in the envelope provided.

The investigator agreed these minor amendments.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation.

With the Committee's best wishes for the success of this project,

Yours sincerely,



Andrea H Torrie
Administrator - West Ethics Committee

E-mail: andrea.torrie@northglasgow.scot.nhs.uk

*Enclosures List of names and professions of members who were present at the
meeting and those who submitted written comments*

Standard approval conditions

Site approval form (SF1)

CHEMOTHERAPY ASSESSMENT CHART

TOXICITY GRADE	TOXICITY	GRADE 0	GRADE 1	GRADE 2	GRADE 3	GRADE 4
	Nausea	None	Able to eat reasonable intake	Intake significantly decreased but can eat	No significant intake	
	Vomiting	None	Once in 24 hours	2-5 times in 24 hours	6-10 times in 24 hours	>10 times in 24 hour requiring IV support
	Diarrhoea	None	Increase of 2-3 stools/day over pre-RX	Increase of 4-6 stools/day or nocturnal stools or moderate cramping	Increase of 7-9 stools/day or incontinence or severe cramping	Increase of >10 stools/day or grossly bloody diarrhoea or need for parental support
	Constipation	None	Requiring stool softener or dietary modification	Requiring laxatives	Constipation requiring manual evacuation or enema	Obstruction or toxic megacolon
	Stomatitis	None	Painless ulcers, erythema or mild soreness	Painful erythema, oedema or ulcers, but can eat	Painful erythema, oedema or ulcers and cannot eat	Required parenteral or enteral support
	Skin	None or No change	Scattered macular or popular eruption or erythema that is asymptomatic	Scattered macular or popular eruption or erythema with purities or other associated symptoms	Generalised symptomatic macular or popular or vesicular eruption	Exfoliative dermatitis or ulcerating dermatitis
	Hand & foot Syndrome	None	Skin changes or dermatitis without pain (eg erythema, peeling)	Skin changes with pain, not interfering with function	Skin changes with pain, interfering with function	
	Alopecia	No loss	Mild hair loss	Pronounced or total hair loss	-	-
	Neuro-sensory	None or no change	Mild paresthesia, loss of deep tendon reflexes	Mild or moderate objective sensory loss; moderate paresthesia	Severe objective sensory loss or paresthesia that interfere with function	-
	Fatigue	None	Increased fatigue over baseline, but not altering normal activities	Moderate or causing difficulty performing some activities	Severe or loss of ability to perform some activities	Bedridden or disabling
Toxicity filled in within protocol		YES	NO			

Medical Comments

--	--

Name

Signature

WHO Performance Status	0	1	2	3	4
Tumour Response					
Unable to Assess	Progression	Stable Disease	Partial Response	Complete Response	Adjuvant
Chemotherapy Prescribed	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Signed		
Outpatient Appointment	Consultant :		Date :	Has Appt <input type="checkbox"/>	To be Made <input type="checkbox"/>
Next Chemotherapy	Place:		Date:	Has Appt <input type="checkbox"/>	To be Made <input type="checkbox"/>

Phase 1 semi-structured interview schedule

Before starting this interview, I would like to remind you that this study is interested in finding out how your life has been since the PICC line was put in, and not the effects of the chemotherapy itself. Try to think of how you feel about the line itself rather than any side effects you might be having because of the treatment.

1. I'd like to start by asking you if you knew what a PICC line was before the nurse or doctor said you might need one?
2. If yes – how did you know?
3. How did you feel about getting the line in?
4. I'd like to find out more now about how the line has changed, if at all, your life on a day today basis. Could you describe to me anything that you find more difficult to do because of the PICC line?
5. Is there anything you find easier to do with the PICC line in?
6. What about other people who live in the house with you or people who may visit you – how do you think they feel about the line?
7. Could you tell me on the whole how the experience of having a PICC line has been?
8. From your experience, what do you think would be useful to tell other patients about having a PICC line in?
9. Is there anything else you would like to tell me about your experience of having a PICC line?

Field-notes

Interview.....

Observation	Comments
Overall opinion of interview	
My performance	
Anything I felt uncomfortable about	
Participant observations; <ul style="list-style-type: none"> • Tone of voice • Body language • When happy • When sad • When angry/uncomfortable • When avoiding 	
Any questions which appeared difficult/misunderstood	
Any unexpected findings	
Anything else of note	

Initial coding of keywords/significant statements

Keyword/statement	Frequency
Liked to help (interview)	1111
Never knew what PICC was (2 knew what PICC was)	1111111
Staying out of hospital was good thing	111111
Uncertainty about procedure prior to placement	1111
Fear of cancer	11111111
Dressing affected	1111111
"Could be worse"	1111111
Fear of cannulation	111111111
Family concerned	111
Grateful to be getting treatment	1111
"you get used to it"	1111111
Fear of pulling line/line falling out	111111111
Fear about being away from hospital/professional help	11111111
Added difficulty with pump attached	111111
Problems washing	1111111
Feeling unclean	11
DN visits restrictive	11
"I'm not complaining"	1111
Protecting others from PICC	111
Didn't like others to see PICC	1111
Good support from DN's	11
Insertion unpleasant	1
Problems sleeping	11111

Need more practical advice	1111111
Fear of spillage	11111
Unprepared for spillage	11
Too much information/information overwhelming	11111111
Other hep's didn't know what to do with PICC	111111
Too much responsibility in patient/family	111
Fear of chemotherapy	11111
Poor information giving re disease/cancer	1
Problems driving	111
Problems playing golf/hill-walking	11
Life restricted	11
Wife affected by line	1
Uncertainty re coping at home	1111
Information too technical	11111
Doctors/nurses responsibilities	11
Doctors/nurses giving information just for the sake of it	1111111
"Scary"/"frightening" experience	111111
"serious" ness of situation	1111
Isolation	1
Not understanding information/feel stupid	1
Don't like line	11
Badge of cancer	111
Guilt re complaining about situation/everyone is so nice	1111
Life not normal	1111
Confidence down	1

APPENDIX XI

Too much negative information/what might go wrong	11111
Fighting spirit	111
Would take PICC again if needed	1111
PICC a good thing/advantages outweigh disadvantages	111
Line becomes part of you	1
No pain during insertion/ease of insertion	1111
Difficulty doing housework/shopping	11
Not able to go on holiday	1
Fear of pump not working	111111
Did not cause problems at all	1

Revised coding of 22 broader categories

Never knew what PICC was

Willingness to help researcher (important for reflexivity)

Fear of disease/treatment

Hobbies affected

Activities of living affected

Affect on family/friends/neighbours/strangers

Grateful for treatment

Fear of cannulation

Need more practical advice

Protecting line

Pump an additional problem

Being out of hospital good

Fear of being away from professional help

Too much responsibility on patient/family

Frightening situation

Life not normal

Unprepared for insertion but ease of insertion

Body image/badge of cancer

Struggle but acceptance/get used to it

Seriousness of situation

Too much information/not the right information

Advantages outweigh disadvantages

Themes identified reflecting interview content

1. effect on daily life
2. information giving
3. coping at home/responsibility
4. adaptation/acceptance

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The impact of a PICC line on the patient receiving cytotoxic chemotherapy.

Before completing this questionnaire, please read the accompanying letter and tick ✓ the boxes beside the statements below to show that you agree with the statements and are happy to take part in the study. Please complete and return the questionnaire to me within two weeks.

- ☐ By completing and returning this questionnaire (version 1.0, October 2004) I understand that I am giving consent for my responses to be used for the purposes of this research project.
- ☐ I confirm that I have read and understood the information sheet and have had the opportunity to ask questions.
- ☐ I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my care being affected in any way.

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Section 1

This section is about you. Please answer the questions as accurately as possible and remember that any information you give will be anonymized.

Please put a tick ✓ in the relevant box.

For office
use only

Q1. Are you? Male ☐ 1 Female ☐ 2

Q1 ☐

Q2. What is your age group?

18 – 39 years ☐ 1

40 – 59 years ☐ 2

60 – 79 years ☐ 3

80 + years ☐ 4

Q2 ☐

Q3. Approximately how many miles do you live away from Ward 4C?

Less than 10 miles ☐ 1

Between 10 and 20 miles ☐ 2

Between 21 and 30 miles ☐ 3

More than 30 miles ☐ 4

Q3 ☐

Q4. Would you say it is easy or difficult for you to get to ward 4C?

Easy ☐ 1 Difficult ☐ 2

Q4 ☐

Q5. When you were first told you might need a PICC line, did you know what a PICC line was?

Yes ☐ 1 No ☐ 2 Can't remember ☐ 3

Q5 ☐

Q6. How many PICC lines have you had FOR THIS COURSE OF CHEMOTHERAPY?

1 ☐ 2 ☐ 3 or more ☐

Q6 ☐

Q7. FOR THIS COURSE OF CHEMOTHERAPY ONLY when was your PICC line first put in?

Date of insertion / /
 DD MM YEAR

If you don't remember the date that the line was put in, can please estimate how many weeks you have had a PICC line in for this course of chemotherapy.

Number of weeks ☐

Please tell me the date you filled in this questionnaire. / /
 DD MM YEAR

Q7 ☐

Section 2

This section is about how you felt when at home with the PICC line.

Please read the statements below. For each statement, please tick ✓ the box to show how much you agree or disagree with the statement.

For
office
use
only

Statement	strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
8. Having a PICC line gives me independence.					
9. I worry that things could go wrong with my PICC line.					
10. I worry about the chemotherapy spilling.					
11. I am happy to take responsibility for my PICC line.					
12. My life is restricted because of the PICC line.					
13. I am relaxed at home with my PICC line.					
14. The PICC line has made my chemotherapy easier to get.					
15. My friends/family worry about my PICC line.					
16. I would have preferred to get my chemotherapy in hospital.					
17. PICC lines give me extra worries when getting chemotherapy.					
18. There is plenty of help and support for people with PICC lines.					
19. I worry that the PICC line will fall out.					

8 ☐

9 ☐

10 ☐

11 ☐

12 ☐

13 ☐

14 ☐

15 ☐

16 ☐

17 ☐

18 ☐

19 ☐

Section 3

This section is about the information you were given about your PICC line.

Please read the statements below. For each statement, please tick ✓ the box to show how much you agree or disagree with the statement.

For
office
use
only

Statement	strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
20. I knew what to expect when the PICC line was put in.					
21. I like to know as much as possible about what is happening to me.					
22. Doctors and nurses tell you things just because they feel they have to.					
23. I had all the information I needed to cope with my PICC line at home.					
24. Too much information is a bad thing.					
25. I was given the choice to have a PICC line or not.					
26. I do not like to be told too much about things that could go wrong.					
27. It is impossible to remember all the information you are given.					
28. The information I was given about my PICC line was just right.					
29. Patients should be told absolutely everything about their PICC line.					
30. Some of the information I was given about my PICC line was quite scary.					

20 ☐

21 ☐

22 ☐

23 ☐

24 ☐

25 ☐

26 ☐

27 ☐

28 ☐

29 ☐

30 ☐

Section 4

This section is about how the PICC line has affected your day to day life.

Please look at the activities below. For every activity, please put a tick ✓ in the box to show if you found the activity any more difficult to do because of the PICC line.

If you did not carry out the activity before you had the PICC line, please tick the box marked N/A.

For
office
use
only

Activity	about the same	a little more difficult	a lot more difficult	can't do because of the PICC	N/A
31. washing myself					
32. bathing					
33. showering					
34. dressing					
35. housework					
36. hobbies					
37. looking after children					
38. relaxing					
39. driving					
40. shopping					
41. sleeping					
42. washing my hair					
43. cooking					
44. other (write below)					

31 ☐

32 ☐

33 ☐

34 ☐

35 ☐

36 ☐

37 ☐

38 ☐

39 ☐

40 ☐

41 ☐

42 ☐

43 ☐

44 ☐

Section 5

This final section is about your thoughts and feelings about having a PICC line in. Again, please look at the statements below and tick ✓ the box to show how much you agree or disagree with each statement.

Statement	strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
45. Having a PICC line is not the sort of thing you ever get used to.					
46. I will do whatever it takes to get my chemotherapy.					
47. It bothers me if strangers see my PICC line.					
48. Having a PICC line is a frightening experience.					
49. I am frightened of needles.					
50. Having a PICC line gets easier the longer you have it.					
51. Having a PICC line is more trouble than it is worth.					
52. I am happy to show my PICC line to anyone.					
53. The good things about a PICC line are more than the bad.					
54. I would recommend a PICC line to other patients.					
55. Patients with PICC lines need more help at the beginning.					
56. It is best to avoid crowds if you have a PICC line.					

45 ☐

46 ☐

47 ☐

48 ☐

49 ☐

50 ☐

51 ☐

52 ☐

53 ☐

54 ☐

55 ☐

56 ☐

Is there anything else you would like to tell me about PICC lines?.....

.....

.....

.....

.....

The questionnaire is now complete. Thank you for your honesty and for taking the time to complete it. Please now post the questionnaire back to me in the envelope provided. Thank you.



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Dd/Mm/Yy

Dear

You were recently approached in Hospital to ask if you would take part in a research study looking into the impact of a PICC lines on patients.

At that time, you stated your willingness to complete a research questionnaire which you took away with you at the time. As yet I have not received your completed questionnaire.

I have included another questionnaire with this letter in case you have lost the one you were given. If this is the case, please complete the questionnaire and return it to me in the envelope provided as soon as you can.

If for any reason you are unable to complete the questionnaire, then no further action is required.

Yours sincerely

Potential Likert scale statements

Statement/theme
Responsibility for line/coping at home
I feel anxious with my PICC line at home
Having a PICC line gives me independence
Being able to get your chemotherapy at home is a good thing
I am relaxed when I am at home with my PICC line
I would have preferred to get my chemotherapy in hospital
A person with a PICC line needs 24 hour support from the hospital even if they are at home
I worry about the chemotherapy spilling
The PICC line has made my chemotherapy easier to get
My life is restricted because of the PICC line
I worry that things could go wrong with my PICC line
There is plenty of help and support for people with PICC lines
I am happy to take responsibility for my PICC line
It is up to the doctors and nurses to look out for problems with the PICC line
Patients are just as capable of knowing when something is wrong as the doctor/nurse
I worry that the PICC line will fall out
My family/friends worry about my PICC line
PICC lines give you extra worries when you are getting chemotherapy
Adaptation/acceptance
It is best to avoid crowds if you have a PICC line
It bothers me if strangers see my PICC line
I would recommend a PICC line to other patients
Having a PICC line gets easier the longer you have it
Having a PICC line is not the kind of thing you ever get used to
Having a PICC line in is a frightening experience
Patients with PICC lines need more help at the beginning
I am frightened of needles
I do not mind getting an injection
I will do whatever it takes to get my chemotherapy
Having a PICC line is more trouble than it is worth
Getting chemotherapy would be easier without a PICC line
On the whole, the good things about a PICC line are more than the bad
I do not like other people to see my PICC line
I am happy to show my PICC line to anyone

Information statements
I felt as though I had all the information I needed to cope with my PICC line at home
The information I was given about my PICC line was just right
Some of the information I was given about my PICC line was quite scary
It is important that patients are told absolutely everything about their PICC line
I would have liked more information about coping with my PICC line at home
Doctors and nurses tell you things just because they feel they have to
It is impossible to remember all the information you are given
I would have liked more information about my PICC line
Getting information before the PICC line is put in makes you less nervous
I do not like to be told too much about things that could go wrong
Too much information is a bad thing
Doctors and nurses should ask the patients how much they want to know about PICC lines
I was given the choice to have a PICC line or not
I felt as if I had to take a PICC line
Patients need to know as much about PICC lines as the doctors and nurses do
I wanted to know more about things that could go wrong with my PICC line
I always like to know as much as possible about things that are happening to me
Getting the PICC line put in was worse than I expected

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